EPA REGISTRATION NUMBER 87895-1 – VOL. 1

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: SEP 3 0 2010		EPA Reg. Number: 71895-R		
	Check List Item	Yes	No	N/A
1	Has the **PRIA Fee been Paid**; is a copy of the check or Pay.gov receipt included in the Submission Package?	X		
2	Is an **Application Form** (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a **Confidential Statement of Formula** (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a **Formulator's Exemption Statement** (EPA Form 8570-27) Included in the Submission Package?		X	
5	Is a **Certification with Respect to Citation of Data** (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a **Data Matrix** (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a **Label** Included in the Submission Package?	X		
8	Are **Data** Included in the Submission Package?	X		
9	**Is the Submission an Amendment?**			

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
87895-1	DEC 22 2011

Term of Issuance:
Conditional

Name of Pesticide Product:
Meymik 15G

Name and Address of Registrant (include ZIP Code):

Ag Logic LLC
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Make the following label change before you release the product for shipment: Revise the EPA Registration Number to read, "EPA Reg. No 87895-1."

2. Submit one copy of the revised final printed label for the record before you release the product for shipment.

3. Storage stability (830.6317) and corrosion characteristics (830.6320) data must be submitted within 18 months from the date of this registration notice.

Signature of Approving Official:
Meredith F. Laws
for John Hebert, Product Manager 7
Insecticide-Rodenticide Branch, Registration Division (7505P)

Date:
DEC 22 2011

EPA Form 8570-6

Additionally, the Basic Confidential Statement of Formula (CSF) dated December 21, 2011, is the only CSF for this product.

EPA is currently reassessing the cumulative impacts of the n-methyl carbamates and that review may impact your product once complete.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. If you have any questions, please contact Jessica Rogala at 703-347-0263 or rogala.jessica@epa.gov.

A stamped copy of the label is enclosed for your records.

John Hebert
Product Manager 7
Insecticide-Rodenticide Branch
Registration Division (7505P)

RESTRICTED USE PESTICIDE

DUE TO ACUTE ORAL TOXICITY and TO GROUND WATER CONTAMINATION

For retail sale to and use only by Certified Applicators or persons under the direct supervision of a Certified Applicator, and only for those uses covered by the Certified Applicator's Certification.

MEYMIK 15G

For Control of Certain Insects, Mites, and Nematodes

ACTIVE INGREDIENT:

Aldicarb [2-methyl-2-(methylthio) propionaldehyde O-(methylcarbamoyl) oxime[	15.0%
OTHER INGREDIENTS:	85.0%
TOTAL:	100.0%

EPA Reg. No. 87895- EPA Est. No.

KEEP OUT OF REACH OF CHILDREN

DANGER POISON

PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

ACCEPTED
DEC 2 2 2011
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pestacide registered under EPA Reg. No. 87895-1

FIRST AID	
IF SWALLOWED:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	• Hold eye open and rinse slowly and gently with warm water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC at 1-800-424-9300 for emergency medical treatment information.	

Aldicarb is an N-methyl carbamate.

See inside label booklet for Precautionary Statements, Directions for Use and Storage and Disposal.

MEDICAL INFORMATION

Contact a physician immediately in all cases of suspected poisoning. Illness may be produced rapidly following overexposure to MEYMIK 15G. If breathing stops, establish an airway and start artificial respiration, and provide oxygen. Make certain to remove all sources of continuing contamination. Remove clothing and wash skin and hair immediately with large amounts of water. Transport the patient to a physician or hospital immediately and SHOW A COPY OF THIS LABEL TO THE PHYSICIAN. If poisoning is suspected in animals, contact a veterinarian.

ANTIDOTE STATEMENT

ATROPINE SULFATE IS HIGHLY EFFECTIVE AS AN ANTIDOTE. See NOTE TO PHYSICIAN.

NOTE TO PHYSICIAN: MEYMIK 15G is an N-methyl carbamate insecticide which is a cholinesterase inhibitor. Overexposure to this substance may cause toxic signs and symptoms due to the cholinergic nervous system. These effects of overexposure are spontaneously and rapidly reversible.

Gastric lavage may be used if this product has been swallowed. MEYMIK 15G poisoning may occur rapidly after ingestion and prompt removal of stomach contents is indicated.

Specific treatment consists of the administration of parenteral atropine sulfate. Caution should be exercised to prevent overatropinization. Mild cases may be given 1 to 2 mg intramuscularly every 10 minutes until full atropinization has been achieved and repeated thereafter whenever symptoms reappear. Severe cases should be given 2 to 4 mg intravenously every 10 minutes until the patient is fully atropinized, then intramuscularly every 30 to 60 minutes as needed to maintain the effect for at least 12 hours. Dosages for children should be appropriately reduced. Complete recovery from overexposure is to be expected within 24 hours.

Narcotics and other sedatives should not be used. Further, drugs such as (pyridine-2-aldoxime methiodide) are NOT recommended unless organophosphate intoxication is also suggested.

To aid in confirmation of a diagnosis, urine samples must be obtained within 24 hours of exposure and immediately frozen. Analyses will be arranged by Ag Logic LLC.

Consultation on therapy can be obtained at all hours by calling CHEMTREC: 1-800-424-9300.

Manufactured for:
Ag Logic LLC
121 S. Estes Drive, Suite 101
Chapel Hill, NC 27514

NET WEIGHT: ____ POUNDS
LOT NO.: _____

PRECAUTIONARY STATEMENTS

HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS

DANGER

FATAL IF SWALLOWED. Causes cholinesterase inhibition. May be fatal or harmful by skin or eye contact or by breathing dust. Rapidly absorbed through skin or eyes. Do not get in eyes, on skin or on clothing. Do not breathe dust. Keep away from domestic animals.

Always stand up-wind from hopper when loading.

SIGNS AND SYMPTOMS OF OVEREXPOSURE:

Salivation, Muscle tremor, Nausea, Watery eyes, Difficult breathing, Vomiting, Pinpoint eye pupils, Excessive sweating, Diarrhea, Blurred vision, Abdominal cramps, Weakness, Headache.

In severe cases, convulsions, unconsciousness, and respiratory failure may occur.

PERSONAL PROTECTIVE EQUIPMENT (PPE) FOR HANDLERS NOT USING CLOSED LOADING SYSTEMS

Some materials that are chemical-resistant to this product are made of any waterproof material. If you want more options, follow the instructions for category A on an EPA chemical-resistant category selection chart.

Personal Protective Equipment (PPE):
All handlers (including loaders and applicators) must wear a minimum of coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material, and chemical-resistant footwear plus socks. In addition, during loading, equipment cleaning or repair, or spill clean up, handlers must wear protective eyewear (goggles or face shield), a chemical-resistant apron, and a NIOSH-approved respirator with a dust/mist filter with the MSHA/NIOSH approval number prefix TC-21C or any N, R, P or HE filter.

Engineering Controls for Enclosed Cab Vehicles:
Applicators using an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] may wear reduced personal protective equipment provided they wear a long-sleeved shirt, long pants, and shoes plus socks and, are provided, have immediately available, and use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant gloves made of any waterproof material, a chemical-resistant apron, chemical-resistant footwear, protective eyewear (goggles or face shield), and a NIOSH-approved respirator with dust/mist filter with the MSHA/NIOSH approval number prefix TC-21C or any N, R, P, or HE filter. Applicators must take off any PPE that was worn in the treated area before reentering the cab, and store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.

USER SAFETY REQUIREMENTS
Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

TOXIC TO FISH, BIRDS, AND OTHER WILDLIFE: This pesticide is extremely toxic to birds and other wildlife. Birds feeding on exposed granules may be killed. Cover or immediately soil incorporate granules spilled during loading, at row ends, or elsewhere to ensure the granules are completely covered with soil.

This pesticide is toxic to fish and aquatic invertebrates. Run-off from treated areas may be hazardous to fish in neighboring areas. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

This product is potentially toxic to honey bees through translocated residues in pollen and nectar is application is made during bloom.

Aldicarb is known to leach through soil into ground water under certain conditions. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination. Apply this product only as specified on this label. Read the use directions and the appended Environmental Precautions and Soil Type Restrictions Tables prior to making applications. If there are any questions, contact Ag Logic LLC at 1-919-932-5800.

DECOMPOSITION AND MOVEMENT IN SOIL: This product is readily decomposed into harmless residues under most use conditions. However, a combination of permeable and acidic soil conditions, moderate to heavy irrigation and/or rainfall, use of 20 or more pounds per acre, and soil temperatures below 50°F (10°C) at application time tend to reduce degradation and promote movement of residues to ground water. If the above describes your local use conditions and ground water in your area used for drinking, do not use this product without first contacting Ag Logic LLC at 1-919-932-5800.

NOTICE: Under the Endangered Species Act, it is a Federal Offense to use any pesticide in a manner that results in the death of a member of an endangered species.

This Act protects Attwater's Greater Prairie Chicken in the Texas counties of Aransas, Austin, Brazoria, Colorado, Galveston, Goliad, Harris, Refugio, and Victoria.

Prior to making applications in these counties, the user must determine that this species is not located in or immediately adjacent to the area to be treated. If the user is in doubt whether or not the above named endangered species may be affected, he should contact either the regional U.S. Fish & Wildlife Service office (Endangered Species Specialist) or personnel of the State Fish and Game office.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
Read entire label before using this product.

Do not apply this product in any way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulations.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours.

Exception: If the product is soil-incorporated or soil-injected, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated. Once the REI has expired, do not allow persons to come into direct contact with treated wet soil as the result of the initial irrigation or rainfall after treatment unless they are wearing the PPE specified below for early entry. PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is coveralls worn over long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material, chemical-resistant footwear plus socks, and protective eyewear.

Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE

Store unused MEYMIK 15G in original container only, in secure, well ventilated clean dry area out of reach of children and animals. Do not store in areas where temperature averages 115°F (46°C) or greater. Do not store in or around the home or home garden.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency or the hazardous waste representative at the nearest EPA regional office for guidance.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If container is burned, stay away from and do not breathe or contact smoke.

IN CASE OF TRANSPORTATION OR WAREHOUSE EMERGENCY INVOLVING A SPILL, FIRE, OR EXPOSURE, CALL CHEMTREC 1-800-424-9300 TWENTY-FOUR HOURS A DAY IN THE USA.

INFORMATION

READ ENTIRE LABEL BEFORE USING THIS PRODUCT.

MEYMIK 15G controls listed insects, mites, and nematodes. When applied into moist soil at planting and/or postemergence the active ingredient aldicarb is rapidly absorbed by roots and translocated to all parts of the plant. Rainfall or irrigation soon after application will ensure prompt uptake of aldicarb; however, if irrigation is necessary, care should be taken not to over irrigate to reduce the potential for residues leaching to ground water. Control often lasts more than six weeks varying with growing conditions, rate of use, and pests. Crop yields are usually increased with treatments of MEYMIK 15G.

RESTRICTIONS

Use MEYMIK 15G only in accordance with label directions, and restrictions. **DO NOT USE ON ANY CROP NOT LISTED ON THIS LABEL OR SUPPLEMENTAL LABELING.** Use higher rates on heavy organic or clay soils. Do not exceed the maximum label rate.

Application may only be made using motorized ground application equipment. Application using aircraft, backpack spreaders, or push-type spreaders is prohibited. Additional restrictions on application equipment pertain to use on sweet potatoes.

Make side-dress applications close enough to plants to allow good uptake by the roots without injury to the plants from root pruning. In irrigated areas, follow application with irrigation within one week. If alternate furrows are irrigated after side-dress application, MEYMIK 15G and water must be on the same side of the plant row.

Calibrate and adjust ground application equipment to ensure proper rate and accurate placement. Clean application equipment thoroughly after use. For any leftover material, see instructions for STORAGE AND DISPOSAL in this booklet.

Deep disk any spills at row ends immediately to prevent birds from feeding on exposed granules.

GROUND WATER RESTRICTIONS

- Observe Environmental Hazard statements regarding Decomposition and Movement in Soil, and carefully follow Directions For Use.
- In fields having soils with less than 15% field moisture holding capacity, special care must be taken not to over-irrigate, since over-irrigation promotes the leaching of chemicals.
- **Do not apply within 50 feet of any drinking water well. More restrictive setbacks may apply. See the *Environmental Precautions and Soil Type Restriction Tables*.**
- Do not wash, load or empty application equipment near any well, as this practice is a potential source of ground water contamination.
- Do not apply this product in the states of Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont or Wisconsin, or in Del Norte or Humbolt counties in California or in Curry County, Oregon.
- For State Specific Ground water Restrictions, see the *Environmental Precautions and Soil Type Restriction Tables.*
- Apply only between March 1 and September 1 when used in California.

ROTATIONAL CROPS RESTRICTIONS

Do not plant any crop not listed on this label in soil treated with MEYMIK 15G within 10 months after the last application with the following exceptions:

Six-month plantback restriction

- Do not plant wheat or barley within 6 months after last application.
- Do not plant bulb crops (such as onions or garlic) within 6 months after the last application.
- Do not plant brassica crops (such as broccoli or cabbage) within 6 months after the last application.

Eight-month plantback restriction

- Do not plant corn within 8 months of last application.
- Do not plant melons within 8 months after last application.
- Do not plant other cucurbits (such as cucumbers and squash) within 8 months after last application.
- Do not plant fruiting vegetables (such as tomatoes or eggplant) within 8 months after the last application.

MEAT AND MILK

- Do not allow livestock to graze in treated areas before harvest.

COMPATIBILITY

Pesticidal activity of MEYMIK 15G is not affected by normal applications of fertilizers or other pesticides. Its effectiveness may be reduced or lost if applied with alkaline materials such as lime. To minimize potential exposure hazards, do not mix MEYMIK 15G with other materials before application.

DIRECTIONS FOR USE

To provide maximum performance and to minimize hazard to birds, granules must be placed into bottom of furrow and immediately covered with soil by mechanical means. For all applications, cover or immediately soil incorporate granules spilled during loading, at row ends, or elsewhere to ensure the granules are completely covered with soil. When a range of rates are specified, use the higher rate if pest infestations are expected to be severe.

COTTON

Crop & Time Of Application	Pests Controlled	Pounds /Acre	EXAMPLE Ounces/1000 Feet of Row	Application Instructions
COTTON At planting In the States of AL, FL, GA and SC, if a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **700 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below the ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.	Aphids, Thrips	3.5 to 5	40" row spacing 4.5 to 6	Apply granules in the seed furrow and immediately cover with soil by mechanical means. If seeds and MEYMIK 15G are hill-dropped, MEYMIK 15G rates may be reduced by one-half.
		(Except Texas, Oklahoma and New Mexico)		
		2 to 5	2.5 to 6	
		(Texas, Oklahoma, and New Mexico Only)		
	Fleahoppers, Leafminers, Mites, Overwintering boll weevil (adults feeding on foliage), Plant bugs, including Lygus	4 to 7	5 to 8.5	
	Nematodes	3.5 to 7	4.5 to 8.5	Apply granules in seed furrow and immediately cover with soil by mechanical means. **OR** Apply granules in a 4 to 6-inch band (T-Band) over open seed furrow and immediately cover with soil by mechanical means.
		(Except California)		
	Aphids, Thrips, Mites, Nematode Suppression (California Only)	5 to 7	6 to 8.5	Apply in seed furrow and cover with soil.
		(California Only)		
Side Dress Application Only or Split Application From 3 weeks after planting through first squaring Side Dress Application only	Suppression of Leafhoppers, Fleahoppers, Mites, Lygus and Nematodes	5	6	Side dress granules in a furrow that is 6 to 10 inches to one or both sides of plant row to a depth of 2 to 3 inches. Adjust applications to minimize root pruning.
		(except California)		
	Suppression of	14 (Californ	17 (California	Apply before populations reach an economic threshold. Apply

Crop & Time Of Application	Pests Controlled	Pounds /Acre	EXAMPLE Ounces/1000 Feet of Row	Application Instructions
In the States of AL, FL, GA and SC, if a **Side Dress** application only is planned and if a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **700 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below the ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. Split Application In the States of AL, FL, GA and SC, if an **At Planting** and **Side Dress** application is planned and if a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **1000 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below the ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.	Leafhoppers, Fleahoppers, Mites, Boll weevil, Plant bugs including Lygus, Cotton leaf perforator, Whiteflies and Nematodes (suppression) . California only.	ia only)	only)	for control of moderate populations. Only suppression may be expected for heavy populations of sweet potato whitefly, especially the poinsettia (B) strain (sliver leaf).

RESTRICTIONS FOR COTTON

- The maximum single at-plant application rate is 7 pounds per acre. See application restrictions on vulnerable soils.
- The maximum single side-dress application rate is 14 pounds per acre in California and 5 pounds per acre in other states. See application restrictions on vulnerable soils.
- Do not exceed a total of 21 pounds per acre per year in California or 12 pounds per acre per year in other states for all applications to cotton. See application restrictions on vulnerable soils where a combination of an At-Planting and Side Dress application is planned.
- Apply only between March 1 and September 1 when used in California.
- Do not make more than one at-planting application and one postemergence application per crop per year.
- Make side-dress applications close enough to plants to allow good uptake by the roots without injury to the plants from root pruning.
- Do not apply within 90 days of harvest.
- Do not feed cotton forage to livestock or allow livestock to graze in treated area.
- Immediately deep-disk any spills at row ends or elsewhere to ensure the granules are covered with a layer of soil.

DRY BEANS

Crop & Time Of Application	Pests Controlled	Pounds/Acre	EXAMPLE Ounces/1000 Feet of Row	Application Instructions
DRY BEANS At planting FOR USE ONLY IN: Colorado, Oregon, Washington, Idaho, and Michigan	Seedcorn maggot	3.5 to 5 (Michigan Only)	36 inch row spacing 4.0 to 5.5	Apply granules in seed furrow and immediately cover with soil by mechanical means. OR Apply in a furrow that is 2 to 3 inches to side of seed row and 2 to 3 inches deep and immediately cover with soil by mechanical means. OR Granules can be placed in seed furrow if the rate does not exceed 5.5 ounces per 1000 feet of row (5 pounds per acre on 36 inch rows).
	Aphids	5 to 7	5.5 to 7.5	
	Leafhoppers Mexican bean beetle Mites	7 to 14	7.5 to 15	
	Nematodes	7 to 14	7.5 to 15	Apply granules in a 4 to 6 inch band and immediately cover with soil by mechanical means. Plant into treated zone. OR Where furrow irrigation is used, apply granules 3 to 4 inches deep and 3 inches from seed row on the water furrow side.

RESTRICTIONS FOR DRY BEANS

- For use only in Colorado, Oregon, Washington, Idaho, and Michigan.

- Do not exceed a total of 14 pounds per acre per season.
- Treatments in excess of 5.5 ounces per 1000 feet of row (5 pounds per acre on 36 inch rows) made directly to the seed furrow may delay plant emergence and reduce plant stand.
- Do not make more than one application per crop per year.
- Do not harvest within 90 days of treatment.
- Do not feed green forage, hay or straw to livestock.
- Do not allow livestock to graze in treated areas before harvest.
- Do not use green pods as food for humans.
- Immediately deep-disk any spills at row ends or elsewhere to ensure the granules are covered with a layer of soil.

PEANUTS

Crop & Time Of Application	Pests Controlled	Pounds /Acre	EXAMPLE Ounces/1000 Feet of Row	Application Instructions
PEANUTS At planting In the States of AL, FL, GA and SC, if a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within 700 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below the ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.	Thrips	7	36" row spacing 7.5	Apply granules in seed furrow and immediately cover with soil by mechanical means. In Southwest United States use high rate only.
	Nematodes	7	7.5	Apply granules in a 4 to 6 inch band over open seed furrow (T-band) and immediately cover with soil by mechanical means. **OR** Apply granules in a 6 to 12 inch band and immediately cover with soil by mechanical means to a depth of 2 to 4 inches. Plant seed into treated zone.
Split Application (Alabama, Florida, Georgia, North Carolina, Oklahoma, Texas and Virginia Only) At time of planting and/or Post-emergence (pegging application) at or just prior to peg initiation but no later	Nematodes	7 At-planting followed by	7.5 At-planting followed by 11	**At-Planting:** Apply granules in a 4 to 6 inch band over open seed furrow (T-band) and immediately cover with soil by mechanical means. **OR** Apply granules in a 6 to 12 inch band and immediately cover with soil by mechanical means to a depth of 2 to 4 inches. Plant seed into treated zone.

Crop & Time Of Application	Pests Controlled	Pounds /Acre	EXAMPLE Ounces/1000 Feet of Row	Application Instructions
than 40 days after emergence and prior to last cultivation. In the States of AL, FL, GA and SC, if an **At Planting** and/or a **Pegging application** is planned and if a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **1100 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below the ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.		10 Post-emergence	Post-emergence	**Post-Emergence:** Apply granules in a band 12 to 18 inches wide on the row and into the plant canopy. Ensure that plant foliage is dry prior to application. Dislodge granules from foliage by suitable means that will not damage the plant. Irrigate immediately after application and complete within 24 hours unless rainfall is received.

RESTRICTIONS FOR PEANUTS

- Do not make more than one application per crop per year in states other than Alabama, Florida, Georgia, North Carolina, Oklahoma, Texas and Virginia.
- The maximum single At-Plant application rate is 7 pounds per acre. See application restrictions on vulnerable soils.
- The maximum single Pegging application rate is 10 pounds per acre. See application restrictions on vulnerable soils.
- Do not exceed a total of 17 pounds per acre per year for all applications to peanuts. See application restrictions to vulnerable soils where a combination of an At-Planting and Pegging application is planned.
- Post-emergence applications are permitted only in fields where overhead irrigation is available.
- Do not make the split application to Spanish peanuts or other short season varieties (a minimum of 90 days is required between pegging applications and harvest).
- Do not harvest within 90 days of application.
- Do not hog-off treated fields.
- Do not allow livestock to graze in treated areas before harvest.
- Do not feed hay or vines to livestock.
- Immediately deep-disk any spills at row ends or elsewhere to ensure the granules are covered with a layer of soil.

SOYBEANS

Crop & Time Of Application	Pests Controlled	Pounds /Acre	EXAMPLE Ounces/1000 Feet of Row	Application Instructions
SOYBEANS At planting **FOR USE ONLY IN:** Georgia, North Carolina, South Carolina, and Virginia In the States of GA and SC, if a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within 700 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below the ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. [NB: No split or pegging language]	Mexican bean beetle Thrips Suppression of three cornered alfalfa hopper	5 to 7	30" row spacing 4.6 to 6.4	Apply granules in seed furrow and immediately cover with soil by mechanical means. Granules may be applied in seed furrow if rate does not exceed 5.5 ounces per 1000 feet of row **OR** If rate exceeds 5.5 ounces per 1000 feet of row (6 pounds per acre on 30 inch rows), apply a 4 to 6 inch band over open seed furrow and immediately cover with soil by mechanical means.
	Nematodes	7	6.4	Apply a 4 to 6 inch band (T-Band) over open seed furrow and immediately cover with soil by mechanical means.

RESTRICTIONS FOR SOYBEANS

- For use only in Georgia, North Carolina, South Carolina, and Virginia.
- Do not make more than one application per crop per year.
- Do not harvest within 90 days of treatment.
- Do not allow livestock to graze in treated areas before harvest.
- Do not feed green forage, hay, or straw to livestock.
- Treatments in excess of 5.5 oz per 1000 feet of row (6 pounds per acre on 30 inch rows) made directly to the seed furrow may delay plant emergence and reduce plant stand.
- Immediately deep-disk any spills at row ends or elsewhere to ensure the granules are covered with a layer of soil.

SUGAR BEETS

Crop & Time Of Application	Pests Controlled	Pounds/ Acre	EXAMPLE Ounces/ 1000 Feet of Row	Application Instructions
SUGAR BEETS At planting or within one week before planting. **FOR USE ONLY IN:** California, Colorado, Idaho, Montana, Nebraska, Oregon, Washington and Wyoming.	Nematodes	27 to 33 (Except California)	22" row spacing 18-22 (Except California)	Apply granules in a 4 to 6 inch band and immediately cover with soil by mechanical means. Plant seed into or above treated zone; **OR** Where furrow irrigation is employed for seed germination, drill granules 3 to 4 inches deep and 3 inches from seed row on water furrow side.
		14 (California Only)	9.5 (California Only)	
At planting	Aphids	7 to14	4.5 to 9.5	Drill granules 1 to 3 inches below seedline. Granules can be placed in seed furrow if rate does not exceed 7 pounds per acre. Repeat applications will be required for continued protection against virus vectors (aphids and leafhoppers)
	Leafminers Leafhoppers	14 to 20 (Except California)	9.5 to 13.5 (Except California)	
		14 (California Only)	9.5 (California Only)	
	Sugar beet root maggot	7 to 14	4.5 to 9.5	Apply granules in a 2 to 3 inch band over seed row and immediately cover with soil by mechanical means. **OR** Where furrow irrigation is employed for seed germination, drill granules 2 inches deep and 2 inches from seed row on water furrow side. For the 7 lb. rate, apply granules in a 1 to 2-inch band in front of the press wheel as the furrow is closing.
At planting plus postemergence (split applications)	Nematodes	14 to 20 at planting and 14 to 20 at postemergence (Except California)	9.5 to 13.5 at planting and 9.5 to 13.5 at postemergence (Except California)	**AT PLANTING:** Apply granules in a 4 to 6-inch band and immediately cover with soil by mechanical means. Plant seed into or above treated zone; **OR** Where furrow irrigation is employed for seed germination, drill granules 3 to
		14 at planting and 14 at postemergence (California Only)	9.5 at planting and 9.5 at postemergence (California Only)	

Crop & Time Of Application	Pests Controlled	Pounds/ Acre	EXAMPLE Ounces/ 1000 Feet of Row	Application Instructions
				4 inches deep and 3 inches from seed row on water furrow side. **POSTEMERGENCE:** Apply granules to both sides of plant row and immediately cover with soil by mechanical means **OR** Where furrow irrigation is employed side-dress granules 4 to 8 inches to water furrow side of plant row at furrow depth. Irrigate soon after application. Apply within 60 days after planting.
Postemergence Do not make any postemergence application if 27 to 33 lbs./acre were applied at planting or one week before planting. Do not make more than one at planting application and two postemergence applications per crop.	Sugar beet root maggot	7 to 14	4.5 to 9.5	Apply granules to both sides of plant row and immediately work into the soil or cover with soil by mechanical means **OR** Where furrow irrigation is employed side-dress granules 4 to 8 inches to water furrow side of plant row at furrow depth. Irrigate soon after application. Apply within 60 days after planting.
	Aphids	7 to 14	4.5 to 9.5	Apply as above. A repeat application may be required for continued protection against virus vectors (aphids, leafhoppers). Apply within 60 days of planting.
	Leafminers Leafhoppers	14 to 20 (Except California)	9.5 to 13.5	
		14 (California Only)	9.5	
	Nematodes	27 (Except California)	18	Apply as above. Apply within 60 days after planting. In California, apply within 30 days after planting.
		14 (California Only)	9.5	

RESTRICTIONS FOR SUGAR BEETS

- For use only in California, Colorado, Idaho, Montana, Nebraska, Oregon, Washington and Wyoming.
- Apply only between March 1 and September 1 when used in California.
- Do not exceed a total of 28 pounds per acre per year in California and 33 pounds per acre per year in other states for all applications to sugar beets.
- Do not make more than one at planting application and two postemergence applications per crop per year.
- Do not apply within 90 days of harvest.
- If tops are to be fed to livestock, do not apply within 120 days of harvest.

- Do not use tops as food for humans.
- Treatments in excess of 4.5 ounces per 1000 feet of row (7 pounds per acre on 22 inch rows) made directly in the seed furrow may delay plant emergence and reduce plant stand.
- Immediately deep-disk any spills at row ends or elsewhere to ensure the granules are covered with a layer of soil.

SWEET POTATOES

Crop & Time Of Application	Pests Controlled	Pounds/Acre	EXAMPLE Ounces/1000 Feet of Row	Application Instructions
SWEET POTATOES Pre-plant or at planting **FOR USE ONLY IN:** Louisiana and Mississippi	Nematodes	10 to 20	48" row spacing 15 to 30	Apply granules in a 12-inch band over open furrow or soil surface and cover immediately during bed forming by mechanically hilling up 8 to 10 inches. Place transplant in center of treated zone.

REQUIRED APPLICATION EQUIPMENT FOR SWEET POTATOES

All applications must be made with Positive Displacement Applicator such as Horstine Microband® or Gandy PDM® or with other Positive Displacement Applicators.

RESTRICTIONS FOR SWEET POTATOES

- For use only in Louisiana and Mississippi.
- Maximum single application rate is 20 pounds per acre per year.
- Do not make more than one application per crop per year.
- Do not harvest within 120 days of application.
- Do not feed sweet potato vines to livestock.
- Immediately deep-disk any spills at row ends or elsewhere to ensure the granules are covered with a layer of soil.

PLANT GROWTH STIMULATION: In the absence of recognizable target pests and under certain growing conditions, stimulation of plant growth by MEYMIK 15G on certain crops has been demonstrated under laboratory, greenhouse, and field conditions. Plants may be visibly taller, greener, and denser. Faster grow-off and an increase in fruiting rate and size often are results of the growth enhancement by MEYMIK 15G. However, such effects do not occur with all crops or under all conditions. Therefore, this product should not be used solely as a plant growth regulator, and its effect as one should be considered a side benefit which may or may not occur as a consequence of its use.

MEYMIK 15G PESTICIDE CALIBRATION GUIDE

APPROXIMATE APPLICATOR SETTINGS* FOR MEYMIK 15G AT 4,5 & 6 MPH

Refer to equipment manufacture literature for additional calibration instructions.

NOTE: This calibration chart is applicable only to MEYMIK 15G in this container which is formulated for use on a corncob carrier. All rates are APPROXIMATIONS and must be confirmed by using a calibration tube (See Calibration Chart provided with tube). Calibration tubes are available from your MEYMIK 15G supplier.

MEYMIK 15G CALIBRATION GUIDE

TYPE OF GRANULAR APPLICATOR

POUNDS MEYMIK 15G PER ACRE FOR VARIOUS ROW SPACINGS

ROW SPACING					GANDY GAUGE SETTING			JOHN DEERE MAX EMERGE GAUGE SETTING**			JOHN DEERE MAX EMERGE II GAUGE SETTING			CASE-1H SERIES 800/900 GAUGE SETTING****		
					MPH			MPH			MPH			MPH		
22"	34"	36"	40"	48"	4	5	6	4	5	6	4	5	6	4	5	6
5.5	3.5	3.3	3	2.5	22	24	27	14	16	18	22	25	29	2/2.0	2/4.5	2/6.5
7.3	4.7	4.4	4	3.3	25	28	30	17	19	21	27	32	37	2/4.5	2/7.5	3/0.0
9.1	5.9	5.5	5	4.2	28	31	33	19	21	23	32	38	44	2/7.5	3/2.0	3/5.0
10.9	7.1	6.7	6	5.0	30	33	35	21	23	25	37	44	48	3/1.0	3/5.5	4/0.0
12.7	8.2	7.8	7	5.8	32	35	37	22	25	26	42	47	50	3/4.5	3/9.0	4/5.0
14.5	9.4	8.9	8	6.7	34	37	39	24	26	28	46	50	52	3/7.0	4/4.0	5/0.0
16.4	10.6	10.0	9	7.5	35	38	41	25	27	29	48	51	54	4/0.0	4/8.0	5/5.0
18.2	11.8	11.1	10	8.3	37	40	43	26	28	30	50	52	55	4/4.0	5/2.0	6/0.0
21.8	14.1	13.3	12	10.0	39	43	47	28	30	33	52	55	57	5/0.0	6/0.0	7/0.0
25.5	16.5	15.6	14	11.7	42	46	50	29	32	35	54	56	60	5/6.5	6/7.5	8/0.0
	18.8	17.8	16	13.3	44	49	54	31	34	37	56	59	62	6/4.0	7/7.5	9/0.0
	21.2	20.0	18	15.0	47	52	59	33	36	38	57	61	65	6/9.5	8/5.0	10/0.0
	23.5	22.2	20	16.7	49	56	66	34	37	40	59	63		7/7.5	9/2.5	11/2.5
			24	20.0	54	66		37	40	44	62			9/0.0	11/0.5	
			27	22.5	59			38	42		65			10/1.0		

*All settings for one hopper box outlet per row

**Odd Numbered Housing (0 – 45)

***Gate/Dial

HORSTINE FARMERY MICROBAND* (Using two 3/16" rotor per outlet, part #094006 POUNDS MEYMIK 15G PER ACRE FOR VARIOUS ROW SPACINGS											
ROW SPACING	SPROCKET** COMBINATION DRIVER/DRIVEN										
	19-34	22-34	25-34	28-34	25-38	22-22	28-25	34-28	34-25	34-22	34-19
22"	5.50	6.40	7.30	8.20	8.90	10.00	11.20	12.10	13.60	15.40	17.80
30"	4.00	4.60	5.30	5.90	6.50	7.30	8.10	8.80	9.90	11.20	13.00
36"	3.30	3.90	4.40	5.00	5.40	6.10	6.80	7.30	8.20	9.40	10.90
40"	3.00	3.50	4.00	4.50	4.80	5.50	6.10	6.60	7.40	8.40	9.80
48"	2.50	2.90	3.30	3.70	4.00	4.60	5.10	5.50	6.20	7.10	8.20
RATIO:	0.550	0.640	0.730	0.820	0.890	1.000	1.120	1.210	1.360	1.545	1.789

- The Microband is based on positive metering. Settings do not need to be changed wilh different tractor speeds.
- All settings for one hopper box outlet per row.
- For alternative dose rates, different width rotors can be fitted. For example, a single 3/4" wide rotor per outlet will deliver twice the rates indicated in the above table.

*Calibrations based upon use of a Horstine Farmery or Canaan 29.5 inch diameter Landwheel drive.

**Sprocket numbers, example: 19-34, indicate number of teeth on the DRIVER and DRIVEN Sprockets.

LIMIT OF WARRANTY AND LIABILITY

Ag Logic LLC warrants that this product conforms to the chemical description on the label and is reasonably fil for the purposes set forth in the Complete Directions for use label booklet ("Directions") when used in accordance with those Directions under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

To the extent consistent with applicable law, buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise. To the extent consistent with applicable law, buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this Company, including, but not limited to, incompatibility with products other than those set forth in the Directions, application to or contact with desirable vegetation, unusual weather, weather conditions which are outside the range considered normal at the application site and for lhe time period when the product is applied as well as weather conditions which are outside the application ranges set forth in the Directions, application in any manner not explicitly set forth in the Directions, moisture conditions outside the moisture range specified in the Directions, or the presence of products other than those set forth in the Directions in or on the soil, crop or treated vegetation.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY, TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.

Upon opening and using this product, buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement. If terms are not acceptable, return at once unopened.

[EPA approval date]

RESTRICTED USE PESTICIDE

DUE TO ACUTE ORAL TOXICITY and TO GROUND WATER CONTAMINATION

For retail sale to and use only by Certified Applicators or persons under the direct supervision of a Certified Applicator, and only for those uses covered by the Certified Applicator's Certification.

MEYMIK 15G

EPA Reg. No. 87895-

Environmental Precautions and Soil Type Restriction Tables

Refer to the container label for additional use precautions and directions.

Ag Logic LLC
12t S. Estes Drive, Suile t0t
Chapel Hill, NC 275t4

ENVIRONMENTAL PRECAUTIONS

GENERAL USE RESTRICTIONS

AGRICULTURAL CHEMICALS HAVE THE POTENTIAL TO MOVE INTO SHALLOW GROUND WATER.

THE FOLLOWING RESTRICTIONS HAVE BEEN DEVELOPED TO PROTECT DRINKING WATER SUPPLIES.

DO NOT APPLY WITHIN 50 FEET OF ANY DRINKING WATER WELL TO MINIMIZE CONTAMINATION BY SURFACE RUNOFF.

MORE STRINGENT RESTRICTIONS MAY BE REQUIRED, AS DISCUSSED BELOW.

Do not wash, load, or empty application equipment near any well, as this practice is a potential source of ground water contamination. In fields having soils with less than 15% field moisture holding capacity, special care must be taken not to over-irrigate, since substantial over-irrigation promotes the leaching of chemicals.

Contact your state pesticide regulatory authority for further information on state requirements for the use of this product.

Some states have or may be developing more restrictive regulations regarding the use and application of MEYMIK t5G. Follow all state regulations restricting the use and application of this product, including limitations on applications near drinking water sources. In all cases, the more restrictive requirements must be followed. It is the responsibility of the applicator to document the construction of wells claimed not to be shallow.

STATE SPECIFIC GROUND WATER LIMITATIONS

Do not apply this product in the states of Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsytvania, Rhode Island, Vermont or Wisconsin, or in Del Norte or Humbolt counties in California or in Curry County, Oregon.

FOLLOW THE LISTED "ADDITIONAL RESTRICTIONS" if the following conditions are present:

STATE	SOILS FOR WHICH RESTRICTIONS APPLY	ADDITIONAL RESTRICTIONS
CO, DE, KS, KY, LA, MD, MO, MS, NC, TN, VA, WV	Loamy sand or sand surface soils and subsoils with an average organic matter in the upper 12 inches of less than 2% by weight. See *SOIL TYPE RESTRICTION TABLES* for specific soil types.	If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within 300 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.
IA, IL, IN, MI, MN, MT, ND, NE, OH, SD, WY	Sandy loam, loamy sand, or sand surface soils, and loamy sand or sand subsoils, with an average organic matter in the upper 12 inches of less than 2% by weight. See *SOIL TYPE RESTRICTION TABLES* for specific soil types.	If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within 500 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.
AL, GA, SC	Vulnerable Cotton and Peanut Soils in AL, GA and SC and Vulnerable Soybean Soils in GA and SC. Loamy sand or sand surface soils and subsoils with an average organic matter in the upper 12 inches of less than 2% by weight See *SOIL TYPE RESTRICTION TABLES* for specific soil types.	**At planting application only to cotton, peanuts or soybeans** If MEYMIK 15G is applied to cotton, peanuts or soybeans as an At-plant application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within 700 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. **Side Dress Application Only or Split Application to cotton** If MEYMIK 15G is applied to cotton as a Side Dress application only and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within 700 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. If MEYMIK 15G is applied to cotton as an At-Plant application and a Side Dress application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within 1000 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. **At-Planting and/or Post emergence application to peanuts** If MEYMIK 15G is applied to peanut as an At-Plant application and/or a Post emergence (Pegging) application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within f100 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. Do not make a post emergence application to peanuts in South Carolina.
FL	Vulnerable Peanut and Cotton Soils Loamy sand or sand surface soils and subsoils with an average organic matter in the upper 12 inches of less than 2% by weight. Any soil classified with a soil hydrologic group of C or D is not considered a restricted soil regardless of other properties.	**At planting application only.** If MEYMIK 15G is applied At-planting to peanuts or cotton and a vulnerable soil is present (see soils listed below) and the water table is less than 25 feet below ground surface, do not apply within 700 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. **Side Dress Application Only or Split Application to cotton** If MEYMIK 15G is applied to cotton as a Side Dress application only and a vulnerable soil is present and the water table is less than 25 feet below ground

<table>
<tr><th>STATE</th><th>SOILS FOR WHICH RESTRICTIONS APPLY</th><th>ADDITIONAL RESTRICTIONS</th></tr>
<tr><td></td><td></td><td>surface, do not apply within <u>700 feet</u> of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to t00 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.
If MEYMIK 15G is applied to cotton as an At-Plant application and a Side Oress application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within <u>1000 feet</u> of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to f00 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

At-Planting and/or Post emergence application to peanuts
If MEYMIK 15G is applied to peanut as an At-Plant application and/or a Post emergence (Pegging) application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within <u>1 t00 feet</u> of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. Do not make a post emergence application to peanuts in South Carolina.

Additional Information
In Florida, it is the responsibility of the applicator to document the construction of wells claimed not to be shallow. This must consist of: (a) a copy of the well completion report issued by the appropriate water management district; or (b) a statement certified as to accuracy by a licensed well contractor. The U.S.O.A. Natural Resources Conservation Service which serves your county can tell you if the soils on your farm fall within the following types of vulnerable soils. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. See Section 5E-2, 028, Florida Administrative Code (F.A.C.), for additional restrictions.
<table>
<tr><td>Adamsville
Alaga
Alpin
Archbold
Astatula
Bigbee
Candler</td><td>Eglin
Florahome
Fort Meade
Foxworth
Gainesville
Kershaw
Klej</td><td>Lake
Lakeland
Neilhurst
Orlando
Orsino
Ortega
Paola</td><td>Penney
Quartzipsamments
Satellite
Tavares
Valdosta</td></tr>
</table></td></tr>
<tr><td>FL</td><td>Other Soils, All Crops</td><td>State regulations require that MEYMIK 15G not be applied within <u>300 feet</u> of any drinking water well. See Section 5E-2, 028, F.A.C., and additional restrictions for peanut and cotton above.</td></tr>
</table>

SOIL TYPE RESTRICTION TABLE

FOLLOW THE LISTED ADDITIONAL RESTRICTIONS IF THE SOIL TYPES ARE PRESENT IN YOUR STATE:

ALABAMA

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. **At planttng application onty:** if MEYMIK 15G is applied to **cotton** or **peanuts** as an At-plant application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **700 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. **Side Dress Application Onty:** If MEYMIK 15G is applied to **cotton** as a Side Dress application only and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **700 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. **Split Apptication:** If MEYMIK 15G is applied to **cotton** as an At-Plant application and a Side Oress application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **t000 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. **At-Plantting and/or Post emergence apptication to peanuts:** If MEYMIK 15G is applied to peanut as an **At-Plant** application and/or a Post emergence (Pegging) application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **1100 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to t00 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

alaga	blanton	corolla	foxworth	lakeland	pactolus
alpin	bruno	crevasse	fripp	latonia	plummer
americus	buncombe	duckston	garcon	teon	saffell
bassfield	chipley	eustis	gorgas	nugent	scranton
bigbee	chipola	flomaton	jones	osier	tarboro

COLORADO

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

bangston	cotopaxi	grieves	littlebear	peetz	stecum
bankard	coyet	grimm	lonetree	pescar	tassel
barcus	crestman	grimstone	luning	pineguest	thoroughfare
baroid	crustown	gunbarrel	mathis	platte	tipper
batterson	dailey	hiwan	maybell	redcreek	tipperary
bijou	dix	inavale	medano	resort	tivoli
blakeland	dunday	ipage	mespun	roswell	tomah
boel	dunul	ironsprings	mido	ruedloff	tomichi
brad	dwyer	juget	mirror lake	ruhe	trail
breece	eachuston	julesburg	moenkopie	ryark	tricera
bresser	ecklund	kandaly	moosed	san isabel	tullock
canlodore	eghelm	kassler	mosca	sawcreek	valent
cascajo	ellicott	kerber	munjor	schamber	valentine
chappell	els	kettle	mysten	schooner	wigton
chaseville	elsmere	kippen	nakai	sheppard	willwood
clark fork	falcon	laird	nesda	siebert	yetull
columbine	farb	laney	newcomb	southace	zeona
comad	farisita	las animas	osgood	space city	
cortena	gilcrest	layoint	ouray	sphinx	
corlett	gracot	legault	pando	spool	
costilla	gretdivid	lincoln	patna	stapleton	

DELAWARE

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to t00 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

downer	galestown	hurlock	osier	rumford	
evesboro	hammonton	kenansville	plummer		
fort mott	hooksan	klej	pocomoke		

SOIL TYPE RESTRICTION TABLE (continued)

GEORGIA

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to f00 feet below ground level or a minimum of 30 feet below the water table. **At planting application only:** if MEYMIK 15G is applied to cotton, peanuts or soybeans as an At-plant application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **700 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to f00 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. **Side Dress Application Only:** If MEYMIK 15G is applied to cotton as a Side Dress application only and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **700 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. **Split Application:** If MEYMIK f5G is applied to cotton as an At-Plant application and a Side Dress application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **1000 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is tess than 25 feet below ground surface. **At-Planting and/or Post emergence application to peanuts:** If MEYMIK 15G is applied to peanut as an At-Plant application and/or a Post emergence (Pegging) application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **1100 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

americus	chipley	fripp	lakeland	ousley	scranton
bigbee	chipola	gorgas	leon	penney	valdosta
blanton	duckston	hurricane	lynn haven	plummer	wateree
boulogne	echaw	johns	mandarin	pottsburg	
buncombe	eustis	kershaw	meadowbrook	ridgeland	
cainhoy	flomaton	kingsferry	molena	ridgewood	
centenary	foxworth	kureb	osier	sapelo	

ILLINOIS

If a vulnerable soil is present and the water table is less than 25 feet, do not apply within **500 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

algansee	carmi	eleva	landes	plainfield	stonelick
alvin	carr	flagler	lanier	princeton	thetford
beavercreek	casco	grable	lorenzo	roby	watseka
billet	chelsea	granby	matherton	rodman	zumbro
bloomfield	chute	hodge	minneiska	saffell	
boone	coloma	homer	morocco	sarpy	
boyer	dickinson	hononegah	oakville	seafield	
brems	disco	hoopeston	oshtemo	sparta	
burkhardt	el dara	lamont	plainbo	spinks	

INDIANA

If a vulnerable soil is present and the water table is less than 25 feet, do not apply within **500 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to f00 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

abscola	bruno	granby	morocco	riverdale	tedrow
algansee	carmi	gravelton	moundhaven	roby	thetford
alvin	casco	hanna	nesius	rodman	tyner
billet	chatterton	homer	newton	saugatuck	wasepi
bloomfield	chelsea	hononegah	oakville	seafield	watseka
bobtown	coloma	hoopeston	ormas	shipshe	zaborosky
boyer	conotton	junius	oshtemo	sisson	zadog
brady	conrad	kosciusko	ouiatenon	sparta	
branch	desker	landes	plainfield	spinks	
brems	dickinson	leoni	princeton	stockland	
bronson	elston	maumee	prochaska	stonelick	

SOIL TYPE RESTRICTION TABLE (continued)

IOWA

If a vulnerable soil is present and the water table is less than 25 feet, do not apply within 500 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

backbone	carr	estherville	hoopeston	oesterle	watseka
billet	chelsea	finchford	klum	perks	zenor
boone	chute	flagler	lamont	salida	
brady	dickinson	fruitfield	lands	sarpy	
buckney	dickman	granby	lilah	sparta	
burkhardt	elrick	hawick	montieth	toolesboro	

KANSAS

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

aline	dwyer	goodnight	kanza	pratt	thurman
bankard	els	gracemore	las animas	sarpy	tivoli
dillwyn	elsmere	haxtun	likes	schamber	valent
dix	goltry	inavale	lincoln	simeon	valentine

KENTUCKY

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to f00 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

bruno	flomaton	lakin	potomac	smithdale	
crevasse	iuka	molena	saffell		

LOUISIANA

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

alaga	bigbee	darden	hackberry	lakeland	osier
bassfield	bruno	eustis	haggerty	latonia	palm beach
betis	cheniere	felicity	hainesville	lotus	peveto
bienville	crevasse	flo	kenney	nugent	

MARYLAND

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

aura	duckston	galestown	klej	newhan	runclint
carteret	evesboro	hammonton	lakeland	osier	
colts neck	fisherman	hooksan	leetonia	plummer	
downer	fort mott	hurlock	leon	pocomoke	
dragston	fripp	ingleside	molena	remlik	

SOIL TYPE RESTRICTION TABLE (continued)

MICHIGAN

If a vulnerable soil is present and the water table is less than 25, do not apply within 500 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

abbaye	chesaning	granby	mahtomedi	padus	spinks
abscota	coloma	grattan	mancelona	pelkie	springlake
adams	coverf	graycalm	manitowish	pemene	st. ignace
alcona	croswell	grayling	matherton	pence	steuben
algansee	cunard	guardlake	maumee	pequaming	sturgeon
allouez	deer park	halfaday	mecosta	perrin	summerville
alpena	deerton	hodenpyl	menahga	peshekee	sundog
alvin	desker	ingalls	millersburg	pipestone	tedrow
arcadian	dickinson	ionia	monico	plainfield	tekenink
arkport	dixboro	ishpeming	montcalm	rapson	thetford
au gres	duel	kalkaska	morocco	richter	trimountain
banat	dunbridge	karlin	nadeau	ridgeville	tyre
battlefield	east lake	kawbawgam	newton	riverdale	vetvet
bixler	eastport	keweenaw	nottawa	rodman	vilas
blue lake	eleva	kingsville	oakville	rousseau	wainola
bohemian	elston	kiva	oconto	rubicon	waiska
boyer	ensign	klacking	ocqueoc	sarona	wallace
brady	esau	koontz	omega	saugatuck	wasepi
branch	evart	kosciusko	onota	sayner	watseka
brems	fabius	landes	ormas	seafield	winterfield
bronson	finch	leelanau	oshtemo	shawano	zeba
channing	freesoil	leoni	otisco	shelldrake	zimmerman
chatham	gilchrist	liming	ottokee	sisson	
chelsea	gladwin	lode	paavola	sparta	

MINNESOTA

If a vulnerable soil is present and the water table is less than 25 feet, do not apply within **500 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

abscota	chelsea	finchford	langola	omega	soderville
alban	chetek	flagler	lasa	osakis	sparta
algansee	claire	fossum	leola	pierz	spinks
alvin	cloquet	friendship	lilah	plainbo	sugarbush
andrusia	conic	gotham	lino	plainfield	torning
anoka	copaston	granby	lohnes	poppleton	ulen
arvilla	cormant	graycalm	maddock	quetico	venlo
beavercreek	cowhorn	hamar	mahtomedi	redby	verndale
becker	cromwell	hawick	marquette	renshaw	wamduska
bellchester	deer park	hecia	meehan	rosholt	watseka
bergkeller	dickinson	hiwood	menahga	rosy	waupaca
billet	dickman	hoopeston	mesaba	salida	wawina
boone	egeland	insula	minneiska	sanburn	winterfield
burkhardt	eleva	kanaranzi	nemadji	sartell	zenor
burnsville	emmert	karlstad	northfield	serden	zimmerman
carmi	evart	kost	nymore	shawano	zippel
caryville	faunce	lamont	oesterle	sioux	zumbro

MISSISSIPPI

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

alaga	bigbee	eustis	latonia	pactolus	st. lucie
bassfield	bruno	flomaton	nugent	plummer	
beulah	crevasse	lakeland	osier	saffell	

MISSOURI

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

alvin	carr	eustis	malden	scotco	
beulah	clana	finchford	plainfield	shelldrake	
bruno	crevasse	hodge	sandbur	sparta	
canalou	diehlstadt	landes	sarpy	wideman	

SOIL TYPE RESTRICTION TABLE (continued)

MONTANA

If a vulnerable soil is present and the water table is less than 25, do not apply within **500 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

alberton	calicott	glendive	mirror	sachet	trey
ambrant	castner	hanly	moiese	sawcreek	tullock
apeldorn	cheadle	haskill	nelson	scravo	turnercrest
ashbon	cheyenne	haverdad	nemote	selle	tusier
ashuelot	chinook	haverty	nesda	selway	twilight
assinniboine	clark fork	havrelon	nippt	seroco	upsata
bangston	cohagen	hiwan	oceanet	sheege	usine
bankard	colburn	jugson	oraid	shingle	utica
banks	comad	kalsted	ovando	shook	valentine
baxendale	como	kirby	pend orielle	shurley	vebar
bearmouth	cowood	krause	poin	splitro	victor
beaverton	cozberg	laporte	redcreek	stecum	virgelle
beenom	dast	larim	rencot	tally	wabek
beisigl	dayschool	lihen	rentsac	tamely	wilsonville
belain	dominic	lisk	rhame	tassel	woodgulch
biglake	dwyer	lolopeak	ridge	terry	woodside
blackhall	elkner	lone rock	riedel	tinsley	worland
blanchard	elmira	lowercreek	riverside	tipperary	yellowbay
bonner	ervide	macfarlane	rivra	tomichi	yetull
brandenburg	flasher	manning	rochester	travessilla	zeona
branham	fleak	mccaffery	ryell	travson	
busby	glaciercreek	mcilwaine	ryorp	treble	
cabba	glenberg	mires	sacheen	trembles	

NEBRASKA

If a vulnerable soil is present and the water table is less than 25 feet, do not apply within **500 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

alda	canyon	duda	hoffland	ord	talmo
almeria	carr	dunday	holt	orphan	tassel
anselmo	cass	dwyer	inavale	ortello	thurman
bankard	chappell	eckley	ipage	orwet	trelona
barney	cheyenne	els	laird	phiferson	treon
bigwinder	craft	elsmere	las animas	pivot	tryon
blendon	dailey	fonner	lute	platte	tuthill
boel	darr	gannett	manter	ronson	valent
bolent	dickinson	glenberg	marlake	sarpy	valentine
boone	dix	gothenburg	mckelvie	schamber	whitelake
brunswick	doger	haverson	meadin	selia	wildhorse
busher	draknab	hedville	munjor	shingle	
calamus		hersh	o'neill	simeon	

NORTH CAROLINA

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

alaga	centenary	galestown	mandarin	pocomoke	tomahawk
alpin	charleston	immokalee	molena	potomac	valhalla
baymeade	chipley	johns	nansemond	pottsburg	wake
biltmore	conetoe	kenansville	newhan	remlik	wakulla
blanton	corolla	klej	norfolk	rimini	wando
bojac	dragston	kureb	ona	rumford	wateree
buncombe	duckston	lakeland	osier	seabrook	
butters	echaw	leon	ostin	st. lucie	
cainhoy	eustis	lillington	ousley	suncook	
candor	foreston	louisburg	pactolus	tarboro	
carteret	fripp	lynn haven	plummer	tolsnot	

SOIL TYPE RESTRICTION TABLE (continued)

NORTH DAKOTA

If a vulnerable soil is present and the water table is less than 25 feet, do not apply within 500 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water tabte. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

appam	chinook	fossum	lohnes	seroco	verendrye
arvilla	claire	glendive	maddock	sioux	virgelle
aylmer	coe	hamar	manning	stirum	wabek
banks	cohagen	hanly	metigoshe	telfer	wamduska
bantry	cormant	haskill	minnewaukan	tinsley	yecross
beisigl	dast	havrelon	osakis	trembles	yetull
binford	desart	hecla	poppleton	trey	zeona
blackhall	egeland	inkster	renshaw	tusler	
blanchard	ekalaka	karlsruhe	rhame	twilight	
brandenburg	falsen	ladner	ruso	ulen	
breien	flasher	lemert	schaller	vebar	
cabba	fleak	lihen	serden	venlo	

OHIO

If a vulnerable soil is present and the water table is less than 25 feet, do not apply within 500 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water tabte is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

abscota	bronson	elnora	lakin	perrin	spinks
algansee	casco	galen	landes	pinegrove	stafford
alvin	coloma	granby	lanier	plainfield	steinsburg
arkport	colonie	hazleton	maumee	princeton	stonelick
barkcamp	conotton	homer	oakville	rodman	tedrow
bixler	dekalb	hoopeston	oshtemo	schaffenaker	tyner
boyer	dixboro	ionia	otisville	sisson	watertown
brady	dunbridge	kingsville	ottokee	sparta	

SOUTH CAROLINA

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within 300 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to f00 feet below ground level or a minimum of 30 feet below the water table. **At planting applicatton only:** if MEYMIK 15G is applied to **cotton, peanuts or soybeans** as an At-plant application and a vulnerable soil is present and the water tabte is less than 25 feet below ground surface, do not apply within 700 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. **Side Dress Application Only:** If MEYMIK f5G is applied to cotton as a Side Dress application only and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within 700 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface. **Sptit Application:** If MEYMIK 15G is applied to **cotton** as an At-Plant application and a Side Dress application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within t000 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water tabte. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

alaga	carteret	eustis	louisburg	pactolus	tomahawk
alpin	centenary	foreston	lynn haven	plummer	wakulla
baratari	charleston	foxworth	molena	pocomoke	wando
baymeade	chipley	fripp	mouzon	ridgeland	wateree
blanton	corolla	johns	murad	rimini	witherbee
brogdon	crevasse	kenansville	nansemond	rosedhu	
buncombe	dragston	kershaw	newhan	scranton	
butters	duckston	kureb	olanta	seabrook	
cainhoy	echaw	lakeland	osier	seewee	
candor	elloree	leon	ousley	tarboro	

SOIL TYPE RESTRICTION TABLE (continued)

SOUTH DAKOTA

If a vulnerable soil is present and the water table is less than 25 feet, do not apply within 500 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

almeria	chinook	flasher	lute	rockoa	tryon
alwilda	cohagen	fleak	maddock	ronson	tusler
anselmo	claire	fossum	manning	sarpy	tuthill
arvilla	craft	gannett	manter	schamber	twilight
assinniboine	dailey	glenberg	marlake	serden	ulen
aylmer	dix	glendive	mawer	seroco	valent
bankard	doger	hamar	mccaffery	shingle	valentine
banks	dogiecreek	hanly	meadin	simeon	vebar
bantry	duda	hecla	minnewaukan	sioux	venlo
beisigl	dunday	henkin	munjor	stirum	wabek
blackhall	dwyer	holt	murdo	storla	whitelake
blendon	eckley	hopdraw	o'neill	talmo	yecross
boel	egeland	inavale	orton	tassel	zeona
butche	ekalaka	ipage	orwet	telfer	
cabba	els	kirby	platte	thurman	
canyon	elsmere	ladner	renshaw	travessilla	
cass	eurldge	las animas	reva	trembles	
chappell	fedora	lihen	rhame	trey	

TENNESSEE

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within 300 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

barkcamp	bruno	crevasse	nugent
bigbee	buncombe	eustis	potomac

VIRGINIA

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within 300 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

alaga	catpoint	fripp	lakin	osier	seabrook
assateague	chipley	galestown	leetonia	ousley	spessard
aura	conetoe	johns	leon	pactolus	tarboro
biltmore	corolla	kenansville	magotha	plummer	wakulla
bojac	dragston	klej	millrock	pocomoke	wando
buncombe	drall	kureb	molena	remlik	wateree
camocca	duckston	lakehurst	nansemond	rumford	
carteret	fisherman	lakeland	newhan	schaffenaker	

WEST VIRGINIA

If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within 300 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

drall	lakin	landes	leetonia	potomac	schaffenaker

SOIL TYPE RESTRICTION TABLE (continued)

WYOMING

If a vulnerable soil is present and the water table is less than 25 feet, do not apply within **500 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.

ashbon	chinook	glenton	meadowlake	rentsac	tipper
adilis	clarkelen	grenoble	means	rivra	tipperary
alcova	comad	grieves	millburne	rogert	tolman
alflack	conpeak	grimm	milok	rohonda	travessilla
anasazi	cordes	grimstone	mishak	roxal	travson
anselmo	corlett	gunbarrel	mosroc	ryark	trelona
apeldorn	cotha	handran	motoqua	ryorp	trembles
assinniboine	cotopaxi	hanks	mudray	sachet	treoff
bankard	cowestglen	hanly	nathale	sawcreek	treon
banks	cowood	hapjack	nelson	schamber	trook
barcus	coyet	haterton	nesda	schooner	troutville
barnum	cragosen	haverdad	newfork	scravo	tullock
baroid	crestman	haverly	nizina	seedskadee	turnback
barrett	crownest	havermom	norriston	sharland	turnercrest
bearmouth	cryluha	hazton	norte	sheege	twilight
beaverton	curabith	hechtman	oceanet	shingle	valent
bigwin	dailey	henrieville	onason	shoshone	valentine
bigwinder	dast	herbman	orphan	shurley	vible
billycreek	derrick	hiland	otterson	sobson	vonason
blackhall	devore	hiwan	ouray	southace	walcott
bobtail	dix	hoot	pahlow	southfork	walden
bodorumpe	draknab	huguston	peetz	space city	wall
bosler	dunday	irigul	pendergrass	splitro	wardboro
bottle	dunul	julesburg	pepton	spool	wendover
boyle	dwyer	kandaly	pescar	stecum	wetmore
branham	eckley	koonich	phiferson	sudworth	whaley
breece	edlin	labou	pilotpeak	sunup	wiggleton
brownsto	elk mountain	lamarsh	pineguest	taluce	willwood
bruja	ellicott	lambman	poin	tassel	wilsonville
busher	emblem	laney	preatorson	tasselman	wint
butche	enos	laporte	pugsley	teagulf	worf
byrnie	ethelman	lariat	quealman	teewinot	worfka
calicott	eyre	larim	quealy	tellman	worfman
cambarge	farisita	las animas	randman	tenorio	worfstone
canwalt	farson	lazear	ratake	terada	worland
carbol	feltner	littlebear	redbank	terro	yetull
cass	fleak	littsan	redcreek	terry	youjay
castner	folavar	lone rock	redfeather	tetonville	zeomont
cathedral	frontier	macfarlane	rekop	theedle	zeona
cestnik	gas creek	manter	relsob	thermopolis	
chappell	glenberg	mathers	rencot	tieside	
cheadle	glendive	mccaffery	reno	tine	

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

September 26, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
ATTN: Jessica Rogala, Product Manager (1RB)

RE: Ag Logic LLC Pending Registration for MEYMIK 15G (EPA File Symbol 87895-R) – [redacted] formulation

Dear Ms. Rogala,

On behalf of Ag Logic LLC, I wanted to send you a letter indicating that at this time, AgLogic will not be pursuing registration of [redacted] formulation with their currently pending MEYMIK 15G application (EPA File Symbol 87895-R).

Please note that this statement does not preclude AgLogic LLC from submitting a separate application for [redacted] aldicarb registration in the near future.

If you have any questions or concerns regarding any of the submission documents, please call me at (253) 853-7369 (office) or (919) 324-2145 (cell) or e-mail me at Leanne@PyxisRC.com at your earliest convenience.

Sincerely,

P. Leanne Pruett

P. Leanne Pruett
Authorized Agent – Ag Logic LLC

Enclosures

cc: A. Puech, Ag Logic, LLC

THIS LETTER CONTAINS **CONFIDENTIAL BUSINESS INFORMATION.**

Manufacturing process information may be entitled to confidential treatment

Updated Meymik 15G label, removing references to [redacted] formulation
Leanne Pruett
to:
Jessica Rogala
08/30/2011 01:08 PM
Cc:
"Antoine A. Puech Ph. D. (AntoinePuech@MEYCORP.com)", Janelle Kay, Ann Tillman
Hide Details
From: Leanne Pruett <Leanne@PyxisRC.com>

To: Jessica Rogala/DC/USEPA/US@EPA

Cc: "Antoine A. Puech Ph. D. (AntoinePuech@MEYCORP.com)" <AntoinePuech@MEYCORP.com>, Janelle Kay <Janelle@PyxisRC.com>, Ann Tillman <Ann@PyxisRC.com>

History: This message has been forwarded.

2 Attachments

087895-xxxxx.20110830.v4-MEYMIK 15G label remove[redacted]PDF.pdf

087895-xxxxx.20110830.v4-MEYMIK 15G label remove[redacted]tracked.PDF.pdf

Hi, Jessica –

Attached, please find the updated MEYMIK 15G label, which removes references to [redacted] formulation.

[redacted] For the corncob grit calibration table, I removed all references which specified corncob (since there is no need to specify) –EXCEPT for one reference in the body of the text which indicates:

"NOTE: This calibration chart is applicable only to MEYMIK 15G in this container which is formulated for use on a corncob carrier."

Manufacturing process information may be entitled to confidential treatment

I felt the specification of the corncob carrier in this case was simply descriptive and should be left on the label.

If you have any questions or concerns or see something that I neglected to modify on this product labeling, please let me know.

Best Regards,
Leanne Pruett
Pyxis Regulatory Consulting

RE: Meymik 15G Label (87895-R)

Leanne Pruett to: Jessica Rogala 08/18/2011 10:15 AM

Cc: "Antoine A. Puech Ph. D. (AntoinePuech@MEYCORP.com)", Janelle Kay, Ann Tillman

History: This message has been forwarded.

2 attachments


087895-xxxxx.20110817.MEYMIK 15G label.v3a.pdf087895-xxxxx.20110817.MEYMIK 15G label.v3a tracked.pdf

Good Morning, Jessica -

Attached, please find updated labeling for AgLogic's MEYMIK 15G. I've got an annotated and unannotated copy attached - the annotated version indicates changes made since the submission of the 6/21/11 version of the label. We've added in the missing county in the Environmental Hazards section of the label, updated the soil tables, and [redacted]

We apologize for using the incorrect soil tables in our previous label, however we did not realize the soil tables had been modified as a result of the MOU (updates soil tables are not attached to current labeling found on EPA's PPLS system). We had to look around and find the newer soil tables in some of Bayer's sales and marketing literature.

I hope this clears up any problems you have with the label. If you require additional changes, please let me know, and I'll address them ASAP.

Regarding the updated stewardship plan, we're currently working on it and should to have it to you very shortly.

Best Regards,
Leanne Pruett
Pyxis Regulatory Consulting

-----Original Message-----
From: Jessica Rogala [mailto:Rogala.Jessica@epamail.epa.gov)
Sent: Thursday, August 04, 2011 12:17 PM
To: Leanne Pruett
Subject: Re: Meymik 15G Label (87895-R)

Hello Leanne,

I'm sorry for not getting this to you sooner. You can probably ignore most of the markings that I made on the label because I was comparing the two for differences. The two major things are the setbacks on pages 21, 22, 23, and 27 as well as a missing county on page 5. Have a pleasant day.

Sincerely,

Jessica Rogala
Environmental Protection Specialist
Insecticide-Rodenticide Branch
Registration Division (Mail Code: 7505P) Office of Pesticide Programs U.S. Environmental Protection Agency

(703) 347-0263

(See attached file: MeymikLabelwErrors.pdf)

Pages 37-55 – *Commercial/financial information may be entitled to confidential treatment*

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OVERNIGHT DELIVERY

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
ATTN: Jessica Rogala, Product Manager (IRB)

August 22, 2011

RE: Ag Logic LLC Stewardship Report – Amended to support MEYMIK 15G (EPA File Symbol 87895-R)

Dear Ms. Rogala,

On behalf of Ag Logic LLC, please find enclosed our amended stewardship plan to support registration of MEYMIK 15G:

1. Product Specific Data (3 copies each):

Volume 1	MEYMIK 15G Aldicarb Stewardship Report – Amended (Study No. PXS-PLP-0811-AM)

If you have any questions or concerns regarding any of the submission documents, please call me at (253) 853-7369 (office) or (919) 324-2145 (cell) or e-mail me at Leanne@PyxisRC.com at your earliest convenience.

Sincerely,

P. Leanne Pruett
Authorized Agent – Ag Logic LLC

Enclosures

cc: A. Puech, Ag Logic, LLC

Pages 57-65 - *Access to FIFRA health and safety data is restricted under FIFRA section 10(g)*

Proposed Registration of Insecticide Aldicarb on Peanuts, Cotton, Sugar Beets, Dry Beans, Soybeans, and Sweet Potatoes

Approved by: Lois Rossi

Lois Rossi, Director
Registration Division

Date: November 16, 2011

Nov. 16, 11

Proposed Registration of the Insecticide Aldicarb on Peanuts, Cotton, Sugar Beets, Dry Beans, Soybeans, and Sweet Potatoes

Regulatory Rationale

The U.S. Environmental Protection Agency (hereon referred to as EPA or the Agency) is proposing to register a pesticide product containing the active ingredient aldicarb.

Regulatory History

Aldicarb is an N-methyl carbamate (NMC) insecticide/nematicide that was first registered in 1970. It is registered on a variety of agricultural crops. It has no residential uses. In 1981, aldicarb was classified as a restricted use pesticide. The Agency reassessed tolerances on food in 2006 and issued the reregistration eligibility decision (RED) for aldicarb in September 2007. Reregistration of aldicarb products was completed in July 2009. Aldicarb has been marketed by Bayer Crop Science under the trade name Temik.

In August 2010, EPA received additional toxicity data from Bayer CropScience showing that aldicarb was more potent than originally estimated in EPA's past risk assessments. At that time, EPA also revised the safety factor for aldicarb for the protection of infants and children to 4.8x (from 2x). In consideration of those changes, EPA conducted a preliminary risk assessment, which indicated that aggregate exposure to the single chemical aldicarb could exceed the Agency's level of concern for infants, children ages 1-2, and children ages 3-5. The critical crop scenarios which appeared to be important to that risk assessment were citrus and potatoes. To address these most significant risks, Bayer Crop Science agreed to end aldicarb use on citrus and potatoes within the year, and to implement additional mitigation for other uses to protect groundwater resources. Please refer to most recent label stamped by EPA on August 16, 2010 and the California 24(c) registration for cotton, for a comprehensive list of label mitigations. The new mitigation measures include:

Citrus/Potatoes

- Bayer has submitted a request under section 6(f) of FIFRA to cancel.
- Existing stocks of aldicarb (Temik® by Bayer) may be sold by retailers, and used on citrus and potatoes only through December 31, 2011.

Cotton

Rate Specifications:

- 1 application per use season in Alabama, Florida, Georgia and South Carolina, applied at planting, at a maximum application rate of 1.05 lbs ai/acre, subject to the drinking water well setbacks as listed below is permitted.

- 1 application per use season in Alabama, Florida, Georgia and South Carolina, applied post emergence as a side dress, at a maximum application rate of 0.75 lbs ai/acre, subject to the drinking water well setbacks as listed below is permitted.
- For a split application consisting of one application at-plant and one application post-emergence, a total maximum of 1.8 lbs ai/acre per acre per year (except for Califomia), subject to the drinking water well setbacks as listed below is permitted.
- For California, the maximum single at-plant application rate is 1.05lbs ai/A. The maximum single side-dress application rate is 2.1 lbs ai/A. A total maximum annual application rate of 3.15lbs ai/A is permitted. Applications can only be made between March 1 and September 1.

Drinking Water Rural Well Setbacks:

- When applied to cotton in Alabama, Florida, Georgia and South Carolina as a single at-plant application or a single post-emergence application, generally, a 700 foot drinking water well setback is required in areas where a vulnerable soil is present (as that term is defined on the labels) and the water table is less than 25 feet below ground surface.
- When applied to cotton as a split application in Alabama, Florida, Georgia and South Carolina consisting of a single at-plant application and a single post emergence application, generally, a 1000 foot drinking water well setback is required in areas where a vulnerable soil is present and the water table is less than 25 feet below ground surface.

Dry Beans

Rate Specifications:

- For use at a seasonal maximum of 2.1lbs ai/A in Colorado, Oregon, Washington, Idaho, and Michigan,
- Only one application per crop per year is permitted.

Peanuts

Rate Specifications:

- 1 application per use season in Alabama, Florida, Georgia and South Carolina, applied at planting, at a maximum application rate of 1.05 lbs ai/acre, subject to the drinking water well setbacks as listed below is permitted.
- 1 application per use season in Alabama, Florida, Georgia and South Carolina, applied post-emergence, at a maximum application rate of 1.5 lbs ai/acre, subject to the drinking water well setbacks as listed below is permitted.
- A split application in Alabama, Florida and Georgia, consisting of one application at-planting, with a maximum application rate of 1.05 lbs/ai/acre and one application post-emergence, with a maximum application rate of 2.55 lbs ai/acre per acre per year, subject to the drinking water well setbacks as listed below is permitted.
- Post-emergence applications are permitted only in fields where overhead irrigation is available. To minimize potential exposure, irrigation must occur immediately after application and complete within 24 hours.

Drinking Water Rural Well Setbacks:

- When applied to peanuts as a single at-plant application in the states of Alabama, Florida, Georgia and South Carolina, generally, a 700 foot drinking water well setback is required in areas where a vulnerable soil is present (as that term is defined on the labels) and the water table is less than 25 feet below ground surface.
- When applied to peanuts as either a single post emergence application (Pegging) or as a split application, consisting of a single at-plant application and a single post emergence (Pegging) application in the states of Alabama, Florida and Georgia, generally, an 1100 foot drinking water well setback is required in areas where a vulnerable soil is present (as that term is defined on the labels), and the water table is less than 25 feet below ground surface.

Soybeans

Rate Specifications:

- 1 application per use season allowed only in the states of Georgia, North Carolina, South Carolina, and Virginia, applied at planting, at a maximum application rate of 1.05 lbs ai/acre, subject to the following drinking water well setbacks listed below is permitted.

Drinking Water Rural Well Setbacks:

- If a vulnerable soil is present (as that term is defined on the labels) in Georgia and South Carolina and the water table is less than 25 feet below ground surface, generally, a 700 foot drinking water well setback is required.

Sugar Beets

Rate Specifications:

- For use at a seasonal maximum application rate up to 4.95lbs ai/A in Colorado, Idaho, Montana, Nebraska, Oregon, Washington and Wyoming
- For use in California, up to 4.2lbs ai/A per year is permitted. Applications may only occur between March 1 and September 1.
- Only one at planting application and up to two postemergence applications per crops are permitted.

Sweet Potatoes

Rate Specifications:

- For use only in Louisiana and Mississippi at a maximum single application rate up to 3 lbs ai/A per year.
- All applications must be made with positive displacement equipment applicators to immediately incorporate granules into the soil.

These mitigations and others identified on the aldicarb label addressed the exposure scenarios which were significant contributors to the risk assessment. However, as a business decision, Bayer opted to voluntarily phase-out (cancel) all of their remaining aldicarb uses (cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes), and therefore Bayer submitted a request for voluntary cancellation of the remaining aldicarb uses, with cancellation to become effective and production to end on December 31, 2014. The Federal Register Notice announcing Bayer's cancellation request was published October 7, 2010. In light of the application at issue here, EPA has not yet granted Bayer's request for voluntary cancellation of the remaining uses.

Pending Application

On September 30, 2010, EPA received an application from AgLogic, LLC to register Meymik® 15G, an end-use product containing aldicarb, for use on peanuts, cotton, sugar beets, dry beans, soybeans, and sweet potatoes. The proposed label for Meymik® is consistent with the current Temik uses, including the mitigations discussed above. The proposed product is to be applied pre-plant, at-plant, and certain post-emergence side dress applications. Meymik's proposed label includes terms and rates which are equivalent to those on the Temik® label, including a California-only use rate on cotton.

After considering the existing aldicarb database and the information included in AgLogic's pesticide application, the Agency is proposing to grant this registration for the requested aldicarb uses. Since the proposed crops are existing uses that are currently registered in the U.S., no new tolerances are being established.

EPA's risk assessments and other support documents can be found by going to the Public Docket found at www.regulations.gov under EPA Docket Number EPA-HQ-OPP-2005-0163.

I. Chemical Information

Chemical Name: Aldicarb
CAS Name: 2-methyl-2-(methylthio)propionaldehyde O- (methylcarbamoyl)oxime
EPA PC Code: 098301

Chemical Abstracts Service (CAS) Number: 116-06-3

Mode of Action: Aldicarb is a systemic insecticide and nematicide. Aldicarb is absorbed by the root system, and is subsequently translocated throughout the plant. Aldicarb is a restricted use pesticide and there is no aldicarb product intended for sale to the general consumer or for use in residential settings. Aldicarb belongs to Group 1 (acetylcholinesterase (AChE) inhibitors) within the Mode of Action classification system developed by the Insecticide Resistance Action Committee.

Applicant: Ag Logic, LLC

Proposed Product: The proposed Meymik® 15G product (EPA File Symbol 87895-R), AgLogic includes all of the same uses and application rates as listed on the Temik® 15G product, with the exception of citrus and potatoes. Those crops are not included on the proposed label submitted by AgLogic. For cotton grown in California, the proposed rate is 2.1 pounds of active ingredient per acre (lbs a.i./A), while the currently registered rate is 1.05 lbs a.i./A, for side dress and split application; this rate is currently approved for use in California under FIFRA Section 24(c). For all other crops, currently registered the application rates range from 0.75 to 4.95 lbs a.i./A. (identical to uses for Temik®)

II. Human Health and Ecological Risk

Because all of the requested crops on the Meymik 15G product are currently registered and for the reasons discussed below, EPA is considering this application pursuant to FIFRA 3(c)(7) as a "me-too" application. See, 40 C.F.R. 152.111. This type of registration request involves a new product which is identical or substantially similar to an existing product relative to its use pattern and product composition. For additional information and the risk assessments in their entirety, please refer to the revised human health risk assessments, dated February 26, 2007, and the revised dietary assessment, dated August 16, 2010. The environmental fate and ecological effects and risks of aldicarb are assessed in the Agency document titled *"Environmental Fate and Effects Division Aldicarb Revised RED"* and "ADDENDUM to: Aldicarb - Ecological risk results for alternative application rate and incorporation efficiencies." These documents are available in the public docket EPA-HQ-OPP-2005-0163 located on-line at http://www.regulations.gov.

III. Data Requirements

AgLogic is relying on the existing database to support the proposed aldicarb end-use product. The available human health and ecological data for the requested aldicarb uses are adequate for assessing hazard and exposure; therefore, no additional confirmatory data are needed at this time to support this registration action in consideration of the proposed terms and conditions.

IV. Benefits Consideration for Aldicarb Uses

In the Aldicarb RED, the Agency evaluated the available alternative insecticides/nematicides for these crops. Cotton and peanut uses were closely considered. The key pests controlled by aldicarb on cotton are aphids, thrips, and nematodes. The key pests controlled in peanuts are thrips and nematodes. By region, aldicarb has been rated for effectiveness. Aldicarb was rated in the Pacific region as Good to Excellent for nematode control in cotton production and as Excellent in the Southeastern region for peanut production. Aldicarb is most important for control of nematodes due to few available alternatives. Aldicarb alternatives for thrips in peanuts are organophospate insecticides. However, aldicarb is noted to provide thrips control for 4+ weeks while the alternatives only provide control for 3 weeks. Alternative nematicides in cotton and peanut production are soil fumigants and though they are rated to be highly efficacious, they have more minimal use due to treatment expense.

V. Proposed Regulatory Decision

Pursuant to the provisions of section 3(c)(4) of FIFRA, the Agency published a notice of receipt (NOR) of the registration application in the *Federal Register* on March 30, 2011 (Docket No. EPA-HQ-OPP-2010-1021). A total of 107 comments were submitted in response to the NOR, which were received from various stakeholders including growers, commodity retailers, farm bureau and other interest groups, and university and state extension specialists. All of the comments received were in favor of registering the proposed aldicarb product, generally stating the following:

1. Aldicarb is one of the less expensive options available to growers.
2. Aldicarb continues to be a highly effective tool against target pests.
3. Growers have great concern over the potential loss of productivity and profit without access to aldicarb.
4. Users have a familiarity with the product and are equipped to use it safely - changing would cost a substantial sum.
5. Without aldicarb, growers would need to rely on other products that are more dangerous, and need to make more applications in the same season to achieve the same level of effectiveness, causing greater environmental/human health damages.

The Agency is proposing to register the aldicarb end-use granular product, AgLogic, LLC's Meymik 15G product on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. The registration determination is proposed under FIFRA section 3(c)(7)(A), on the basis that the Meymik pesticide is identical to or substantially similar to an existing registered pesticide.

Aldicarb will begin registration review in 2012. The Registration Review program ensures that as the ability to assess risk evolves and as policies and practices change, all registered products continue to meet the FIFRA statutory standard of no unreasonable adverse effects. Also, aldicarb belongs to the n-methyl carbamate group of pesticides which all share a common mechanism of toxicity. The Food Quality Protection Act (FQPA) of 1996 directs EPA to consider available information on the cumulative effects on human health resulting from exposure to multiple pesticide chemicals that have a common mechanism of toxicity. The n-methyl carbamate group is currently undergoing evaluation.

Posting an FDMS Docket without a Federal Register Notice

MEMORANDUM

SUBJECT: Posting EPA-HQ-OPP-2010-1021 to Regulations.gov for Public Access

TO: Office of Pesticide Programs Docket

FROM: Lois Rossi
Director, Registration Division
Office of Pesticide Programs

Lois Rossi November 16, 2011

This memorandum authorizes the posting of EPA-HQ-OPP-2010-1021to Regulations.gov for public access.

Proposed Registration of Insecticide Aldicarb on Peanuts, Cotton, Sugar, Beets, Dry Beans, Soybeans, and Sweet Potatoes.

This document will be open for public comment from **11/16/2011** to **12/16/2011**.

Submit your comments, identified by Docket ID No. EPA-HQ-OPP-2010-1021, by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.
- Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- Hand Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

EPA's policy is that all comments received will be included in the public docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise

protected through http://www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through http://www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, avoid any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at http://www.epa.gov/epahome/dockets.htm.

Should you have any questions regarding this memorandum, please contact Jessica Rogala at (703) 347-0263, or via email at rogala.jessica@epa.gov.

Registration of the Insecticide Aldicarb on Peanuts, Cotton, Sugar Beets, Dry Beans, Soybeans, and Sweet Potatoes

Approved by: Lois Rossi

Lois Rossi, Director
Registration Division

Date: December 22, 2011

Registration of the Insecticide Aldicarb on Peanuts, Cotton, Sugar Beets, Dry Beans, Soybeans, and Sweet Potatoes

Regulatory Rationale

The U.S. Environmental Protection Agency (hereon referred to as EPA or the Agency) is conditionally granting the registration of a pesticide product containing the active ingredient aldicarb.

Regulatory History

Aldicarb is an N-methyl carbamate (NMC) insecticide/nematicide that was first registered in 1970. It is registered on a variety of agricultural crops. It has no residential uses. In 1981, aldicarb was classified as a restricted use pesticide. The Agency reassessed tolerances on food in 2006 and issued the reregistration eligibility decision (RED) for aldicarb in September 2007. Reregistration of aldicarb products was completed in July 2009. Aldicarb has been marketed by Bayer Crop Science under the trade name Temik.

In August 2010, EPA received additional toxicity data from Bayer CropScience showing that aldicarb was more potent than originally estimated in EPA's past risk assessments. At that time, EPA also revised the safety factor for aldicarb for the protection of infants and children to 4.8x (from 2x). In consideration of those changes, EPA conducted a preliminary risk assessment, which indicated that aggregate exposure to the single chemical aldicarb could exceed the Agency's level of concern for infants, children ages 1-2, and children ages 3-5. The critical crop scenarios which appeared to be important to that risk assessment were citrus and potatoes. To address these most significant risks, Bayer Crop Science agreed to end aldicarb use on citrus and potatoes within the year, and to implement additional mitigation for other uses to protect groundwater resources. Please refer to most recent label stamped by EPA on August 16, 2010 and the California 24(c) registration for cotton, for a comprehensive list of label mitigations. The new mitigation measures include:

Citrus/Potatoes

- Bayer has submitted a request under section 6(f) of FIFRA to cancel.
- Existing stocks of aldicarb (Temik® by Bayer) may be sold by retailers, and used on citrus and potatoes only through December 31, 2011.

Cotton

Rate Specifications:

- 1 application per use season in Alabama, Florida, Georgia and South Carolina, applied at planting, at a maximum application rate of 1.05 lbs ai/acre, subject to the drinking water well setbacks as listed below is permitted.

- 1 application per use season in Alabama, Florida, Georgia and South Carolina, applied post emergence as a side dress, at a maximum application rate of 0.75 lbs ai/acre, subject to the drinking water well setbacks as listed below is permitted.
- For a split application consisting of one application at-plant and one application post-emergence, a total maximum of 1.8 lbs ai/acre per year (except for California), subject to the drinking water well setbacks as listed below is permitted.
- For California, the maximum single at-plant application rate is 1.05 lbs ai/acre. The maximum single side-dress application rate is 2.1 lbs ai/acre. A total maximum annual application rate of 3.15 lbs ai/acre is permitted. Applications can only be made between March1and September 1.

Drinking Water Rural Well Setbacks:

- When applied to cotton in Alabama, Florida, Georgia and South Carolina as a single at-plant application or a single post-emergence application, generally, a 700 foot drinking water well setback is required in areas where a vulnerable soil is present (as that term is defined on the labels) and the water table is less than 25 feet below ground surface.
- When applied to cotton as a split application in Alabama, Florida, Georgia and South Carolina consisting of a single at-plant application and a single post emergence application, generally, a 1000 foot drinking water well setback is required in areas where a vulnerable soil is present and the water table is less than 25 feet below ground surface.

Dry Beans

Rate Specifications:

- For use at a seasonal maximum of 2.1 lbs ai/acre in Colorado, Oregon, Washington, Idaho, and Michigan,
- Only one application per crop per year is permitted.

Peanuts

Rate Specifications:

- 1 application per use season in Alabama, Florida, Georgia and South Carolina, applied at planting, at a maximum application rate of 1.05 lbs ai/acre, subject to the drinking water well setbacks as listed below is permitted.
- 1 application per use season in Alabama, Florida, Georgia and South Carolina, applied post-emergence, at a maximum application rate of 1.5 lbs ai/acre, subject to the drinking water well setbacks as listed below is permitted.
- A split application in Alabama, Florida and Georgia, consisting of one application at-planting, with a maximum application rate of 1.05 lbs ai/acre and one application post-emergence, with a maximum application rate of 2.55 lbs ai/acre per year, subject to the drinking water well setbacks as listed below is permitted.
- Post-emergence applications are permitted only in fields where overhead irrigation is available. To minimize potential exposure, irrigation must occur immediately after application and complete within 24 hours.

Drinking Water Rural Well Setbacks:

- When applied to peanuts as a single at-plant application in the states of Alabama, Florida, Georgia and South Carolina, generally, a 700 foot drinking water well setback is required in areas where a vulnerable soil is present (as that term is defined on the labels) and the water table is less than 25 feet below ground surface.
- When applied to peanuts as either a single post emergence application (Pegging) or as a split application, consisting of a single at-plant application and a single post emergence (Pegging) application in the states of Alabama, Florida and Georgia, generally, an 1100 foot drinking water well setback is required in areas where a vulnerable soil is present (as that term is defined on the labels), and the water table is less than 25 feet below ground surface.

Soybeans

Rate Specifications:

- 1 application per use season allowed only in the states of Georgia, North Carolina, South Carolina, and Virginia, applied at planting, at a maximum application rate of 1.05 lbs ai/acre, subject to the following drinking water well setbacks listed below is permitted.

Drinking Water Rural Well Setbacks:

- If a vulnerable soil is present (as that term is defined on the labels) in Georgia and South Carolina and the water table is less than 25 feet below ground surface, generally, a 700 foot drinking water well setback is required.

Sugar Beets

Rate Specifications:

- For use at a seasonal maximum application rate up to 4.95 lbs ai/acre in Colorado, Idaho, Montana, Nebraska, Oregon, Washington and Wyoming
- For use in California, up to 4.2 lbs ai/acre per year is permitted. Applications may only occur between March 1 and September 1.
- Only one at planting application and up to two postemergence applications per crop are permitted.

Sweet Potatoes

Rate Specifications:

- For use only in Louisiana and Mississippi at a maximum single application rate up to 3 lbs ai/acre per year.
- All applications must be made with positive displacement equipment applicators to immediately incorporate granules into the soil.

These mitigations and others identified on the aldicarb label addressed the exposure scenarios which were significant contributors to the risk assessment. However, as a business decision, Bayer opted to voluntarily phase-out (cancel) all of their remaining aldicarb uses (cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes), and therefore Bayer submitted a request for voluntary cancellation of the remaining aldicarb uses, with cancellation to become effective and production to end on December 31, 2014. The Federal Register Notice announcing Bayer's cancellation request was published October 7, 2010. In light of the application at issue here and consistent with past policy, EPA has not yet administratively processed Bayer's request for voluntary cancellation of the remaining uses.

On September 30, 2010, EPA received an application from AgLogic, LLC to register Meymik® 15G, an end-use product containing aldicarb, for use on peanuts, cotton, sugar beets, dry beans, soybeans, and sweet potatoes. The proposed label for Meymik® is consistent with the current Temik uses, including the mitigations discussed above. The proposed product is to be applied pre-plant, at-plant, and certain post-emergence side dress applications. Meymik's proposed label includes terms and rates which are equivalent to those on the Temik® label, including a California-only use rate on cotton.

After considering the existing aldicarb database and the information included in AgLogic's pesticide application, and the comments received during the 30-day public comment period, the Agency is conditionally registering Meymik® 15G. Since the crops on the Meymik® 15G label are existing uses that are currently registered in the U.S., no new tolerances are being established.

EPA's risk assessments and other support documents can be found by going to the Public Docket found at www.regulations.gov under EPA Docket Number EPA-HQ-OPP-2005-0163.

I. Chemical Information

Chemical Name: Aldicarb
CAS Name: 2-methyl-2-(methylthio)propionaldehyde O- (methylcarbamoyl)oxime
EPA PC Code: 098301

Chemical Abstracts Service (CAS) Number: 116-06-3

Mode of Action: Aldicarb is a systemic insecticide and nematicide. Aldicarb is absorbed by the root system, and is subsequently translocated throughout the plant. Aldicarb is a restricted use pesticide and there is no aldicarb product intended for sale to the general consumer or for use in residential settings. Aldicarb belongs to Group 1 (acetylcholinesterase (AChE) inhibitors) within the Mode of Action classification system developed by the Insecticide Resistance Action Committee.

Registrant: Ag Logic, LLC

Proposed Product: The proposed Meymik® 15G product (EPA File Symbol 87895-R), AgLogic includes all of the same uses and application rates as listed on the Temik® 15G

product, with the exception of citrus and potatoes. Those crops are not included on the proposed label submitted by AgLogic. For cotton grown in California, the proposed rate is 2.1 pounds of active ingredient per acre (lbs a.i./A), while the currently registered rate is 1.05 lbs a.i./A, for side dress and split application; this rate is currently approved for use in California under FIFRA Section 24(c). For all other crops, currently registered the application rates range from 0.75 to 4.95 lbs a.i./A. (identical to uses for Temik®)

II. Human Health and Ecological Risk

Because all of the requested crops on the Meymik 15G product are currently registered and for the reasons discussed below, EPA is considering this application pursuant to FIFRA 3(c)(7) as a "me-too" application. See, 40 C.F.R. 152.111. This type of registration request involves a new product which is identical or substantially similar to an existing product relative to its use pattern and product composition. For additional information and the risk assessments in their entirety, please refer to the revised human health risk assessments, dated February 26, 2007, and the revised dietary assessment, dated August 16, 2010. The environmental fate and ecological effects and risks of aldicarb are assessed in the Agency document titled *"Environmental Fate and Effects Division Aldicarb Revised RED"* and "ADDENDUM to: Aldicarb - Ecological risk results for alternative application rate and incorporation efficiencies." These documents are available in the public docket EPA-HQ-OPP-2005-0163 located on-line at http://www.regulations.gov.

III. Data Requirements

AgLogic is relying on the existing database to support the proposed aldicarb end-use product. The available human health and ecological data for the requested aldicarb uses are adequate for assessing hazard and exposure; therefore, no additional confirmatory data are needed at this time to support this registration action in consideration of the proposed terms and conditions.

IV. Benefits Consideration for Aldicarb Uses

In the Aldicarb RED, the Agency evaluated the available alternative insecticides/nematicides for these crops. Cotton and peanut uses were closely considered. The key pests controlled by aldicarb on cotton are aphids, thrips, and nematodes. The key pests controlled in peanuts are thrips and nematodes. By region, aldicarb has been rated for effectiveness. Aldicarb was rated in the Pacific region as Good to Excellent for nematode control in cotton production and as Excellent in the Southeastern region for peanut production. Aldicarb is most important for control of nematodes due to few available alternatives. Aldicarb alternatives for thrips in peanuts are organophosphate insecticides. However, aldicarb is noted to provide thrips control for 4+ weeks while the alternatives only provide control for 3 weeks. Alternative nematicides in cotton and peanut production are soil fumigants and though they are rated to be highly efficacious, they have more minimal use due to treatment expense.

V. Regulatory Decision

Pursuant to the provisions of section 3(c)(4) of FIFRA, the Agency published a notice of receipt (NOR) of the registration application in the *Federal Register* on March 30, 2011 (Docket No. EPA-HQ-OPP-2010-1021). A total of 107 comments were submitted in response to the NOR, which were received from various stakeholders including growers, commodity retailers, farm bureau and other interest groups, and university and state extension specialists. All of the comments received were in favor of registering the proposed aldicarb product, generally stating the following:

1. Aldicarb is one of the less expensive options available to growers.
2. Aldicarb continues to be a highly effective tool against target pests.
3. Growers have great concern over the potential loss of productivity and profit without access to aldicarb.
4. Users have a familiarity with the product and are equipped to use it safely - changing would cost a substantial sum.
5. Without aldicarb, growers would need to rely on other products that are more dangerous, and need to make more applications in the same season to achieve the same level of effectiveness, causing greater environmental/human health damages.

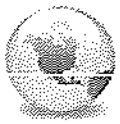
On November 16, 2011, the Agency posted the proposed decision document for Meymik® 15G entitled "Proposed Registration of Insecticide Aldicarb on Peanuts, Cotton, Sugar Beets, Dry Beans, Soybeans, and Sweet Potatoes," the associated risk assessments and the proposed label in docket ID number, EPA-HQ-OPP- 2010-1021. Two public comments in support of the proposed decision were received, one from the California Cotton Ginners and Growers Association, and the other from the National Cotton Council. The California Cotton Ginners and Growers Association noted that 1,000 California growers support the registration of Meymik® 15G. They stated that their primary reason for supporting the registration is the lack of effective alternatives. They noted that the potential alternatives require multiple applications that are less effective and more costly. The National Cotton Council, which represents producers, ginners, oilseed crushers, merchants, cooperatives, textile manufacturers, and cottonseed handlers in 17 states expressed support for the registration. The NCC commented that use of aldicarb reduces a grower's need for additional foliar pesticide sprays. They cited research that demonstrates that aldicarb treated plots had higher yields of both cotton fiber and cottonseed, than plots not treated with aldicarb.

No other comments were submitted on the proposed registration decision for Meymik® 15G.

Aldicarb will begin Registration Review in 2012. The Registration Review program ensures that as the ability to assess risk evolves and as policies and practices change, all registered products continue to meet the FIFRA statutory standard of no unreasonable adverse effects.

Based on these considerations, consistent with the requirements of FIFRA section 3(c)(7)(A), EPA concludes that (i) it has satisfactory data pertaining to the proposed uses of Meymik® 15 G, an end-use product containing aldicarb, on peanuts, cotton, sugar beets, dry beans, soybeans and sweet potatoes; (ii) approving this application as set forth above will not cause unreasonable adverse effects on the environment; and (iii) the registration of Meymik® 15G is in the public

interest. Accordingly, the Agency is conditionally granting the registration of the aldicarb end-use granular product Meymik® 15G for use on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes under FIFRA section 3(c)(7)(A), on the basis that the Meymik pesticide is identical to or substantially similar to an existing registered pesticide. The registration is granted conditionally because aldicarb belongs to the n-methyl carbamate group of pesticides which all share a common mechanism of toxicity. The Food Quality Protection Act (FQPA) of 1996 directs EPA to consider available information on the cumulative effects on human health resulting from exposure to multiple pesticide chemicals that have a common mechanism of toxicity. The n-methyl carbamate group is currently undergoing evaluation. The Meymik registration will be subject to any regulatory decisions that are made during and at the conclusion of the cumulative assessment.



RE: Fwd: Meymik 15G EPA File Symbol 87895-R
Leanne Pruett to: John Hebert 12/15/2011 03:53 PM
Cc: Jessica Rogala

Thanks, John -

If the package is sitting on Lois's or Steve Bradbury's desk, and you think a call from a congressional rep. might help move it along, please let me know, and Antoine can ask one of his congressional supporters to give a call.

If you'd like to give me a call, you can most easily reach me on my cell phone, at (919) 324-2145.

Best,
Leanne

-----Original Message-----
From: Hebert.John@epamail.epa.gov (mailto:Hebert.John@epamail.epa.gov]
Sent: Thursday, December 15, 2011 3:48 PM
To: Leanne Pruett
Cc: Rogala.Jessica@epamail.epa.gov
Subject: Re: Fwd: Meymik 15G EPA File Symbol 87895-R

Leanne - Thanks. We've prepared the renegotiation for signature. I'm sure either Jessica or me will be in touch with you next week.

John Hebert, PM7
Insecticide-Rodenticide Branch
Registration Division
Office of Pesticide Programs
703-308-6249

From: Leanne Pruett <Leanne@PyxisRC.com>
To: John Hebert/DC/USEPA/US@EPA
Date: 12/15/2011 03:15 PM
Subject: Fwd: Meymik 15G EPA File Symbol 87895-R

Hi, John - it's important for AgLogic to have this registration in place in time for the Beltwide Cotton Conference, so we'd like to have the registration action completed by Dec 22.

I'm put of office moe, but will call you when I get in.

Best,
Leanne

Sent from my iPhone

Begin forwarded message:

From: "Antoine Puech" <antoinepuech@meycorp.com>
To: "Leanne Pruett" <Leanne@PyxisRC.com>
Cc: "Janelle Kay" <Janelle@PyxisRC.com>

Hi Leanne - Today is the PRIA due date for this registration action.
However, as you probably know the 30 day comment period for the proposed
decision will not end until Dec. 17. To date, we've only received two
comments - both in favor of the registration. The next step in the public
process is to tweak the Proposed Decision into a final decision document
which will include the two comments. Since this may need to go up the
management chain for review we would like to renegotiate the PRIA due date
to December 30. Please let me know if this date is acceptable.

Regards,
John

John Hebert, PM7
Insecticide-Rodenticide Branch
Registration Division
Office of Pesticide Programs
703-308-6249

<2012 Beltwide.pdf>
<Temik Beltwide Article.pdf>
<California cotton growers comments. Dec. 2011.pdf>
<NCC comments Dec. 2011.pdf>

Recommendation of Division Directors
Negotiated Due Dates

Decision #: 440582	Registration #: 87895-R	Petition #: NA

☐ *See page 2 for additianal registration entries*

Chemical Name: Aldicarb

Fee Category: R330	**PRIA Decision Time Frame:** 12 months	
Submitted by: John Hebert	**Branch:** OCSPP/OPP/RD	**Date:** 12/15/2011

Company: Ag Logic

Original PRIA Due Date: 10/23/2011	**Proposed New PRIA Due Date:** 12/22/2011

Previous Negotiated Due Dates: 11/04/2011 12/15/2011

Is the "Fix" in-house? ☐ Yes ☐ No ☑ n/a	**If not, date "Fix" expected:**

Negotiated Due Date Reason:

Additional Data Required	☐ Product Chemistry	☐ Toxicology	☐ Acute Tox	☐ Environmental	
	☐ Efficacy	☐ Ecological	☐ Residue	☐ Other	
Data Deficiencies	☐ Product Chemistry	☐ Acute Tox	☐ Efficacy	☐ Residue	☐ Toxicology
	☐ Environmental	☐ Ecological	☐ Labeling	☐ Other	☐ Not Submitted
Late Risk Assessment	☐ Human Health	☐ Ecological			
Interim Consideration	☐ Agency Initiated	☐ Registrant Initiated			

☐ CSF	☑ Public Process	☐ Risk Issues Environmental	☐ Risk Issues Human Health
☐ Impurities Review	☐ Label	☐ Administrative-FR Notice	☐ Other – Comment Field

Summary of Deficiency Type(s): ☐ **Not Submitted (N)** ☐ **Deficiencies (D)**

Product Chemistry: ☐ **Acute Tox:** ☐ **Efficacy:** ☐ **Labeling:** ☐ **Ecological Data:** ☐ **Other (describe):** ☐

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

Requested (Dec. 15) a new due date of Dec. 30, 2011 to allow to summarize the comments from the public docket and prepare the final decision document for the public process.

"75 Day" Letter sent? ☐ **Yes, Date sent** ☑ **No and reason for none?** *Add comments on page 2*

Rationale for Proposed Due Date: Allow time to finalize the public process.

Registrant notified that this is the last negotiation? ☐ **Yes** ☑ **Not Applicable**

Approve: ☑	**Disapprove:** ☐

If disapproved, action to be taken:

OD or DOD Signature: *CN=William Jordan/OU=DC/O=USEPA/C=US*	**Date:** *12/16/2011*

Decision #: 440580	Registration #:87895-R	Petition #:

Issue(s) (describe in detail):

This registration action is subject to the public process and the proposed decision is currently undergoing public comment. The 30 day comment period will end on Dec. 17. As of now there have only been two comments submitted - both in favor of the registration. The additional time is needed to complete the public process by preparing the final decision document (which will include/address all comments received during the comment period) and for management review and approval. The registrant would only agree to a one week extension.

Comment(s):

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv4a.pdf
Form Number: PRIA
Document Identifier: PRIA-11349162018-JH

SUBMITTED on 12/15/2011 at 04:35:55 PM by CN=John Hebert/OU=DC/O=USEPA/C=US

APPROVED on 12/15/2011 at 04:39:56 PM by CN=Meredith Laws/OU=DC/O=USEPA/C=US

APPROVED on 12/15/2011 at 04:45:03 PM by CN=Dan Rosenblatt/OU=DC/O=USEPA/C=US

TAKEN BACK on 12/16/2011 at 12:30:41 PM by CN=John Hebert/OU=DC/O=USEPA/C=US

SUBMITTED on 12/16/2011 at 12:42:33 PM by CN=John Hebert/OU=DC/O=USEPA/C=US

TAKEN BACK on 12/16/2011 at 12:45:41 PM by CN=John Hebert/OU=DC/O=USEPA/C=US

SUBMITTED on 12/16/2011 at 12:48:45 PM by CN=John Hebert/OU=DC/O=USEPA/C=US

APPROVED on 12/16/2011 at 12:50:22 PM by CN=John Hebert/OU=DC/O=USEPA/C=US

APPROVED on 12/16/2011 at 01:05:40 PM by CN=Dan Rosenblatt/OU=DC/O=USEPA/C=US

REROUTED on 12/16/2011 at 05:28:39 PM by CN=Elizabeth Leovey/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 12/16/2011 at 05:39:17 PM by CN=William Jordan/OU=DC/O=USEPA/C=US

PRIA Renegotion for AgLogic, LLC Meymik 15G (EPA File Symbol 87895-R) until December 15th, 2011
Leanne Pruett
to:
John Hebert
11/04/2011 02:46 PM
Cc:
Jessica Rogala, "Antoine A. Puech Ph. D. (AntoinePuech@MEYCORP.com)", Ann Tillman, Janelle Kay
Hide Details
From: Leanne Pruett <Leanne@PyxisRC.com>

To: John Hebert/DC/USEPA/US@EPA

Cc: Jessica Rogala/DC/USEPA/US@EPA, "Antoine A. Puech Ph. D. (AntoinePuech@MEYCORP.com)" <AntoinePuech@MEYCORP.com>, Ann Tillman <Ann@PyxisRC.com>, Janelle Kay <Janelle@PyxisRC.com>

Dear Mr. Hebert -

I am writing to you on behalf of AgLogic LLC regarding the pending registration application for Meymik 15G (EPA File Symbol 87895-R) containing aldicarb as the active ingredient. The initial PRIA date for this application was October 23rd, 2011, and a PRIA date of November 4th was renegotiated with AgLogic on October 18th, 2011.

Based on yesterday's telephone conversation between you and I, I understand that the Public Participation posting document is complete, but has not yet been signed or posted to the EPA website.

We are very disappointed that the decision document was not posted by November 4th. We would like EPA to make every possible effort to post this document during the week of November 7th – 11th.
At this time, we will agree to a PRIA extension until **December 15th, 2011.** We understand that this means the Meymik 15G decision document will be posted to the EPA website on or before November 14th, 2011, and that (barring any substantive comments) the registration will be issued and AgLogic LLC will receive the registration certificate and stamped, accepted label by December 15th, 2011.

AgLogic requests that it be contacted immediately upon any delay.

Sincerely,

P. Leanne Pruett
Pyxis Regulatory Consulting, Inc.
Authorized Agent, AgLogic, LLC

Recommendation of Division Directors
Negotiated Due Dates

Decision #: 440580	Registration #: 87895-R	Petition #: NA

☐ *See page 2 for additional registration entries*

Chemical Name: Aldicarb

Fee Category: R330	**PRIA Decision Time Frame:** 12 months	
Submitted by: John Hebert	**Branch:** OCSPP/OPP/RD	**Date:** 11/04/2011

Company: AgLogic LLC

Original PRIA Due Date: 10/21/2011	**Proposed New PRIA Due Date:** 12/15/2011

Previous Negotiated Due Dates: 11/04/2011

Is the "Fix" in-house? ☐ Yes ☐ No ☑ n/a	**If not, date "Fix" expected:**

Negotiated Due Date Reason:

Additional Data Required	☐ Product Chemistry	☐ Toxicology	☐ Acute Tox	☐ Environmental	
	☐ Efficacy	☐ Ecological	☐ Residue	☐ Other	
Data Deficiencies	☐ Product Chemistry	☐ Acute Tox	☐ Efficacy	☐ Residue	☐ Toxicology
	☐ Environmental	☐ Ecological	☐ Labeling	☐ Other	☐ Not Submitted
Late Risk Assessment	☐ Human Health	☐ Ecological			
Interim Consideration	☐ Agency Initiated	☐ Registrant Initiated			

☐ CSF	☑ Public Process	☐ Risk Issues Environmental	☐ Risk Issues Human Health
☐ Impurities Review	☐ Label	☐ Administrative-FR Notice	☐ Other – Comment Field

Summary of Deficiency Type(s): ☐ **Not Submitted (N)** ☐ **Deficiencies (D)**

Product Chemistry: ☐ **Acute Tox:** ☐ **Efficacy:** ☐ **Labeling:** ☐ **Ecological Data:** ☐ **Other (describe):** ☐

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

The registrant's consultant, Pyxis Regulatory Consulting, Inc. was contacted on Nov. 3 to discuss the pending PRIA due date and the need to renegotiate to allow for time for the public process.

"75 Day" Letter sent? ☐ **Yes, Date sent** ☑ **No and reason for none?** *Add comments on page 2*

Rationale for Proposed Due Date: To allow time to post the Agency's proposed decision (Pub. Process)

Registrant notified that this is the last negotiation? ☐ **Yes** ☑ **Not Applicable**

Approve: ☑	**Disapprove:** ☐

If disapproved, action to be taken:

OD or DOD Signature: *CN=Marty Mone///OU=DC/O=USEPA/C=US*	**Date:** *11/04/2011*

Decision #:	Registration #:	Petition #:

Issue(s) (describe in detail):

The extra timing is required to allow for the Agency's proposed decision to go through the public process with a 30 day comment period.

Comment(s):

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv4a.pdf
Form Number: PRIA
Document Identifier: PRIA-11308142431-JH

SUBMITTED on 11/04/2011 at 02:54:42 PM by CN=John Hebert/OU=DC/O=USEPA/C=US

APPROVED on 11/04/2011 at 03:00:20 PM by CN=John Hebert/OU=DC/O=USEPA/C=US

APPROVED on 11/04/2011 at 03:16:41 PM by CN=Dan Rosenblatt/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 11/04/2011 at 03:34:25 PM by CN=Marty Monell/OU=DC/O=USEPA/C=US

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

October 18, 2011

ELECTRONIC AND COURIER DELIVERY

Meredith Laws
Document Processing Desk
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: AgLogic LLC.
Meymik 15G (EPA File Symbol 87895-R)
Response to Request for a PRIA Extension

Dear Ms. Laws:

I am writing to you on behalf of AgLogic LLC regarding the pending registration application for Meymik 15G (EPA File Symbol 87895-R) containing aldicarb as the active ingredient. I understand that Jessica Rogala has spoken with Leanne Pruett of our offices requesting a PRIA extension of 60 days to December 21, 2011 to allow the Agency time to complete the 30 day Federal Register posting and finalize the registration for Meymik 15G.

AgLogic and Pyxis are concerned about this PRIA extension request for several reasons. We are extremely disappointed in EPA's abrupt and last minute delay in handling of this action, particularly in light of the fact that this is a me-too registration, and the EPA is fully aware that lack of aldicarb availability in the United States causes a grave economic hardship to cotton producers. We have made EPA aware of problems caused by the shortage of aldicarb in our previous meetings and continue to receive numerous calls from users and consultants extremely anxious about its projected availability. In fact, AgLogic have twice requested irate producers not to bombard EPA and Congress with phone calls protesting delays in registration. .

During our meeting with EPA in July of this year, we asked for expedited review of Meymik 15G because Bayer CropScience had ceased the manufacture of aldicarb and unexpectedly exited the aldicarb market, permanently ending availability of their Temik 15G to growers.

As we explained at that time (and in our August 2, 2011 letter to EPA), the Meymik 15G aldicarb formulation is an extremely slow process and each batch of Meymik 15G takes many hours to prepare. With this long formulation time, Ag Logic respectfully requested EPA grant the registration in an expedited and timely manner to allow sufficient time to formulate adequate inventory and obtain state registrations needed to meet growers' needs for the beginning of the 2012 season.

The aldicarb use season is very short, as it starts in late February and ends in early May. With little or no inventory, and long production lead times, this delay is making it improbable (if not impossible) for AgLogic to meet grower's needs for the spring growing season.

Recommendation of Division Directors
Negotiated Due Dates

Decision #: 440580	Registration #: 87895-R	Petition #:

☐ *See page 2 for additional registration entries*

Chemical Name: Aldicarb

Fee Category: R330	**PRIA Decision Time Frame:** 2 weeks	
Submitted by: Jessica Rogala	**Branch:** OCSPP/OPP/RD	**Date:** 10/19/2011

Company: Ag Logic LLC

Original PRIA Due Date: 10/21/2011	**Proposed New PRIA Due Date:** 11/04/2011

Previous Negotiated Due Dates:

Is the "Fix" in-house? ☑ Yes ☐ No ☐ n/a	**If not, date "Fix" expected:**

Negotiated Due Date Reason:

Additional Data Required	☐ Product Chemistry	☐ Toxicology	☐ Acute Tox	☐ Environmental	
	☐ Efficacy	☐ Ecological	☐ Residue	☐ Other	
Data Deficiencies	☐ Product Chemistry	☐ Acute Tox	☐ Efficacy	☐ Residue	☐ Toxicology
	☐ Environmental	☐ Ecological	☐ Labeling	☐ Other	☐ Not Submitted
Late Risk Assessment	☐ Human Health	☐ Ecological			
Interim Consideration	☑ Agency Initiated	☐ Registrant Initiated			

☐ CSF	☑ Public Process	☐ Risk Issues Environmental	☐ Risk Issues Human Health
☐ Impurities Review	☐ Label	☐ Administrative-FR Notice	☐ Other – Comment Field

Summary of Deficiency Type(s): ☐ **Not Submitted (N)** ☐ **Deficiencies (D)**

Product Chemistry: ☐ **Acute Tox:** ☐ **Efficacy:** ☐ **Labeling:** ☐ **Ecological Data:** ☐ **Other (describe):** ☐

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

Company had expressed a wish to move up the possible deadline but has been very understanding about the need to move through the public process.

"75 Day" Letter sent? ☐ **Yes, Date sent** ☑ **No and reason for none?** *Add comments on page 2*

Rationale for Proposed Due Date: Necessary time to complete public process

Registrant notified that this is the last negotiation? ☐ **Yes** ☑ **Not Applicable**

Approve: ☑	**Disapprove:** ☐

If disapproved, action to be taken:

OD or DOD Signature: *CN=William Jordan/OU=DC/O=USEPA/C=US*	**Date:** *10/20/2011*

Decision #: 440580	Registration #:87895-R	Petition #:

Issue(s) (describe in detail):

Need to renegoniate the October 21, 2011 deadline to accomodate time for public process. - Company refused the proposed two month extension but is willing to give a 2 week extension.

Comment(s):

The Aldicarb product proposed by Ag Logic LLC is essentially a me too of a Bayer registration. Because Bayer had iniatiated the process of cancelling aldicarb it was decided that the new registration of Aldicarb by Ag Logic go through the public process to garner public opinion and maintain transparency of the Agency's actions. The comments from the first public comment period were overwhelmingly in favor of the registration of AgLogic's Aldicarb product. The extension is needed to post one Decision Document with a 30day comment period. The Document has been drafted and is awaiting review by OGC. The agency proposed a two month extension of the PRIA deadline. The company refused citing that this is an unusual process for a "me too" application and that they have complied with all of OPP/RD's requests. They proposed a 2 week extension deadline.

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv4a.pdf
Form Number: PRIA
Document Identifier: PRIA-11287155201-JR

SUBMITTED on 10/19/2011 at 03:37:12 PM by CN=Jessica Rogala/OU=DC/O=USEPA/C=US

TAKEN BACK on 10/19/2011 at 04:41:34 PM by CN=Jessica Rogala/OU=DC/O=USEPA/C=US

SUBMITTED on 10/19/2011 at 04:48:33 PM by CN=Jessica Rogala/OU=DC/O=USEPA/C=US

TAKEN BACK on 10/20/2011 at 03:59:24 PM by CN=Jessica Rogala/OU=DC/O=USEPA/C=US

SUBMITTED on 10/20/2011 at 04:03:27 PM by CN=Jessica Rogala/OU=DC/O=USEPA/C=US

APPROVED on 10/20/2011 at 04:19:05 PM by CN=Marion Johnson/OU=DC/O=USEPA/C=US

APPROVED on 10/20/2011 at 04:20:17 PM by CN=Dan Rosenblatt/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 10/20/2011 at 04:22:31 PM by CN=William Jordan/OU=DC/O=USEPA/C=US

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 14, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PYXIS REGULATORY CONSULTING, INC
AG LOGIC LLC
4110 136TH ST. NW
GIG HARBOR, WA 98332-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 30-SEP-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

File Copy

October 22, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-440580
EPA File Symbol or Registration Number: 87895-R
Product Name: MEYMIK 15G
EPA Receipt Date: 30-Sep-2010
EPA Company Number: 87895
Company Name: AG LOGIC LLC

JANELLE KAY
PYXIS REGULATORY CONSULTING, INC
AG LOGIC LLC
4110 136TH ST. NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action previously identified as R310 has been reclassified as Action Code: R330

NEW MANUFACTURING USE PRODUCT;OLD AI;SELECTIVE CITATION;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,
Front End Processing Staff
Information Technology & Resources Management Division

Change (BACK!!!) in PRIA Code

John Hebert to: John Jamula 10/21/20 10 04:48 PM
Cc: Stephen Schaible

Hey JJ - I hope that your policy of holding onto $$$ for awhile before you issue a refund still stands. Anyway, the RD PRIA committee met today and decide that:

EPA File Symbol 87895-R
S-883212

should be an R330. That is the code the registrant requested when the package was submitted. Thanks and sorry about the coding issues on this one. Thanks.

john

John Hebert, PM7
Insecticide-Rodenticide Branch
Registration Division
Office of Pesticide Programs
703-308-6249

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 9-30-10

Experts In-Processing Signature: MF Harrington Date 10-5-10 Fee Paid: Yes ✓

Division management contacted on issues No ____ Yes ____ Date ____

EPA Reg. Number: 87895-R	EPA Receipt Date: 9-30-10

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	**yes** X	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	**yes** X	**no**			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)			
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. Sce Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

KL
- studies associated w/ jacket (MRID 182508) have not passed 86-5 review
- Vol. 2, pg 6 is illegable & pg 76-205 are missing
- Corrections for all deficiencies have been received

- jacket passes

MRID 482508

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

MEYMIK 15 G Formulation

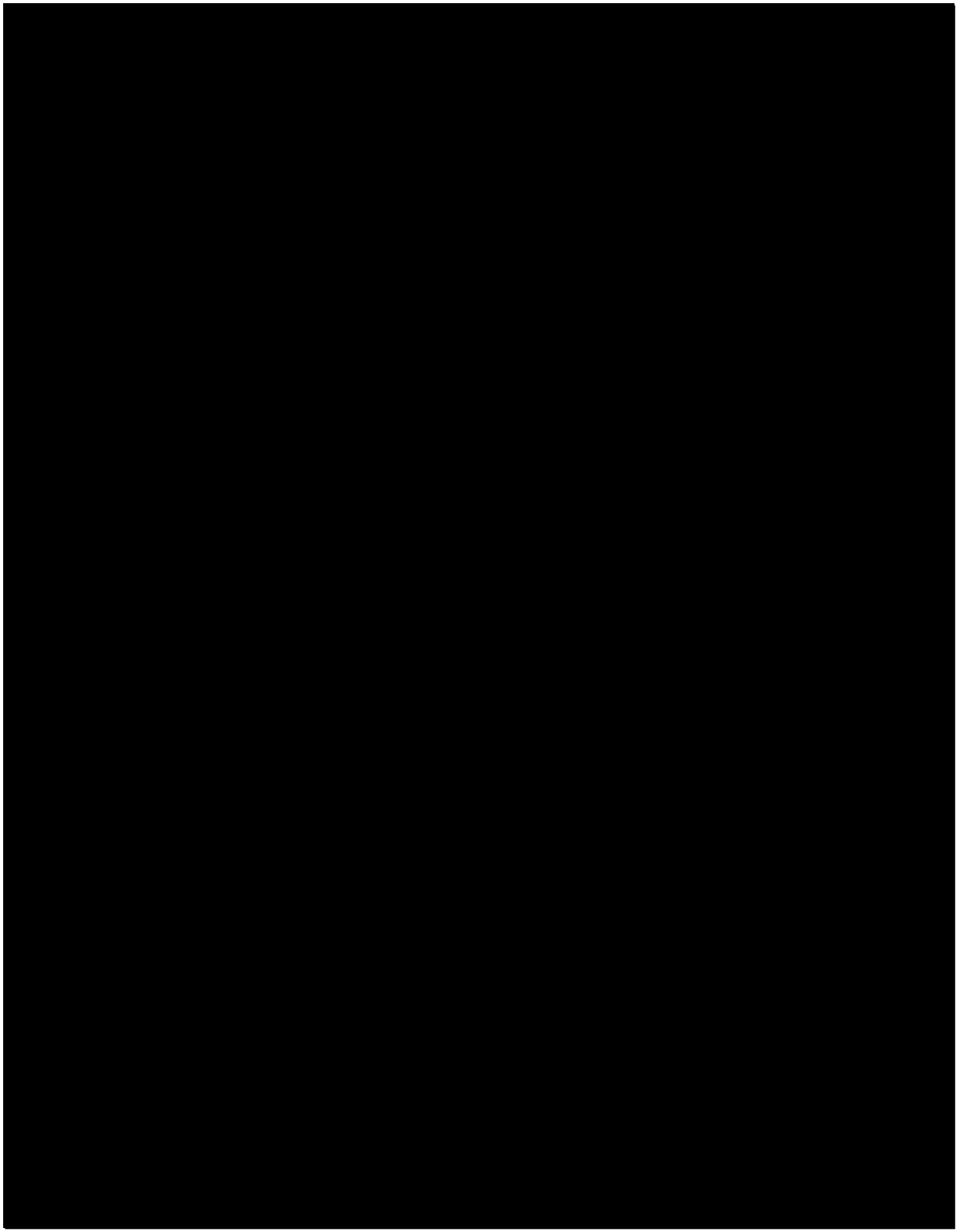
Acute Toxicity Data

Table 1. Acute Toxicity of Aldicarb.

Guideline No./Study Type	MRID No.	Results	Toxicity Category
Acute oral toxicity - Rat	00057333	LD_{50} = 0.8 mg/kg/day	I
Acute dermal toxicity – Rabbit	00091241	LD_{50} = 20 mg/kg/day, water	I
Acute inhalation toxicity- Rat	00069916	LC_{50} = < 0.007 mg/L	I

[redacted]

Manufacturing process information may be entitled to confidential treatment



Decision #: 440580

DP #: (385365)

PRIA

Parent DP #:

Submission #: 883212

DATA PACKAGE BEAN SHEET

Date: 16-Jun-2011

* * * Registration Information * * *

Registration: 87895-R - MEYMIK 15G

Company: 87895 - AG LOGIC LLC

Risk Manager: RM 07 - John Hebert - (703) 308-6249 Room# PY1 S-7227

Risk Manager Reviewer: Autumn Metzger AMETZGER

Sent Date: Calculated Due Date: 21-Oct-2011 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R330) NEW MANUFACTURING USE PRODUCT;OLD AI;SELECTIVE CITATION;

Ingredients: 098301, Aldicarb(15%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 06-Jan-2011 Due Back:

DP Ingredient: 098301, Aldicarb

DP Title: ACUTE TOXICITY

CSF Included: ● Yes ◯ No Label Included: ◯ Yes ● No Parent DP #:

Assigned To		Date In	Date Out	
Organization:	RD / TRB	10-Jan-2011		Last Possible Science Due Date: 23-Jun-2011
Team Name:	TOX			Science Due Date:
Reviewer Name:				Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

Please reviw the following data submission to support this new product. Enclosed are: cover letter from company, CSFs, data matrix (pages citing acute tox only) and data.

thanks,
Autumn/ John Hebert

DP#: (385365) *** Studies Sent for Review *** Decision#: (440580)

MRID	MRID Status	Citation Reference	Guideline
48250807		Tillman, A. (2010) Aldicarb 15% G Acute Toxicity. Project Number: ME/201004, BIDI/9/4039, 50606. Unpublished study prepared by Microquim S.A. 162 p.	870.1100/Acute Oral Toxicity
48250807		Tillman, A. (2010) Aldicarb 15% G Acute Toxicity. Project Number: ME/201004, BIDI/9/4039, 50606. Unpublished study prepared by Microquim S.A. 162 p.	870.1200/Acute dermal toxicity
48250807		Tillman, A. (2010) Aldicarb 15% G Acute Toxicity. Project Number: ME/201004, BIDI/9/4039, 50606. Unpublished study prepared by Microquim S.A. 162 p.	870.2400/Acute eye irritation
48250807		Tillman, A. (2010) Aldicarb 15% G Acute Toxicity. Project Number: ME/201004, BIDI/9/4039, 50606. Unpublished study prepared by Microquim S.A. 162 p.	870.2600/Skin sensitization
48250807		Tillman, A. (2010) Aldicarb 15% G Acute Toxicity. Project Number: ME/201004, BIDI/9/4039, 50606. Unpublished study prepared by Microquim S.A. 162 p.	870.2500/Acute dermal irritation
48250807		Tillman, A. (2010) Aldicarb 15% G Acute Toxicity. Project Number: ME/201004, BIDI/9/4039, 50606. Unpublished study prepared by Microquim S.A. 162 p.	870.1300/Acute inhalation toxicity

DATA EVALUATION RECORD

ALDICARB
(MEYMIK 15G)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)
Description of Materials Used to Produce the Product (OPPTS 830.1600)
Description of the Formulation Process (OPPTS 830.1650)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRIDs 482508-01 through 482508-06

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Summitec Corporation
9724 Kingston Pike, Suite 602
Knoxville, Tennessee
Task Order No. 3-A-33

Primary Reviewer:
Thomas C. Marshall, Ph.D.

Signature: _____
Date: _____

Secondary Reviewers:
Eric B. Lewis, M.S.

Signature: _____
Date: _____

Robert Ross, M.S., Program Manager

Signature: _____
Date: _____

Quality Assurance:
Angie Edmonds, B.S.

Signature: _____
Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

FEE

DP BARCODE No.: 385364; **FILE SYMBOL No.**: 87895-R; **PRODUCT NAME**: MEYMIK 15G; **DECISION No.**: 440580; **PC Code(s)**: 098301 **ACTION CODE**: R330; **FOOD Use**: Yes

DATE OUT: June 29, 2011

SUBJECT: End Use Product Chemistry Review
Product Name: MEYMIK 15G (containing unregistered source of AI aldicarb)

FROM: Shyam Mathur
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

S Bmathur 6/29/11
DMC

TO: Autumn Metzger / John Hebert, PM 07
Insecticide-Rodenticide Branch / RD (7505P)

Company Name: Ag Logic LLC
Formulation Type: Insecticide

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product "MEYMIK 15G." An un-registered source of the active ingredient (aldicarb) is used in the formulation of the proposed end use product. The unregistered active ingredient aldicarb is [redacted]

The registrant has submitted a basic CSF and four alternate CSF's (all dated 09-23-10). In support of the registration application, the registrant has submitted 830 series group A product chemistry data with MRID Nos. 482508-01, -02, -03, & -04, and 830 series group B data with MRID Nos. 482508-04, -05, & -06 for the proposed end use product and for the unregistered aldicarb tgai/mup. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 264-330. The primary review on the data submitted was conducted by Summitec Corporation, Knoxville, TN. TRB has been asked to determine the acceptability of basic CSF, four alternate CSF's and the supporting product chemistry data and also determine similarity to the registered product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Aldicarb (15.0% a.i.)

2. Has the registrant claimed substantial similarity to a registered product?
[X] Yes; [ ] No; [ ] NA; if yes, give the registration number of the cited product.
EPA Reg. No: 264-330

3. All of the source materials of the active ingredient are derived from registered sources- [ ] Yes; [X] No:

An unregistered preparation of technical grade aldicarb prepared by the registrant is proposed for this product. Attachment 1 to this DER provides a review of the material submitted for the production of technical grade aldicarb (see page #9).

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses.

5. Confidential Statement of Formula(s):

[X] Basic - Dated: 9/23/2010; Re-submitted - Dated: 06/20/11

[X] Alternate 1 CSF – Dated 9/23/2010; Re-submitted – Dated: 06/20/11

[X] Alternate 2 CSF – Dated 9/23/2010; Re-submitted – Dated: 06/21/11

[X] Alternate 3 CSF – Dated 9/23/2010; Re-submitted – Dated: 06/20/11

[X] Alternate 4 CSF – Dated 9/23/2010; Re-submitted – Dated: 06/20/11

Alternate CSF(s) complies with 40CFR§152.43: [X] Yes; [ ] No; [ ] NA

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

[X] Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

[X] Yes; [ ] No; if not, explain below

Metallic equivalent:	[ ] Yes	[X] NA;
Soluble arsenic:	[ ] Yes	[X] NA
Isomeric ratios:	[ ] Yes	[X] NA
Acid Equivalent:	[ ] Yes	[X] NA; acid equivalent =

b. Health related sub statements: Product contains?

The label was not available to the reviewer.
Petroleum distillate at > 10%: [ ] Yes [X] No [ ] NA
Methanol at > 4%: [ ] Yes [X] No [ ] NA
Sodium nitrate/sodium nitrite [ ] Yes [X] No [ ]

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

[ ] Yes [X] No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

[ ] Yes; [ ] No; [X] NA; if not, explain below

d. Label requires an additional Storage and Disposal statement: [ ] Yes [X] No; if yes explain below:

7. Group **A**: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	482508-01
830.1600	Description of materials used to produce the product		X		A	482508-01
830.1650	Description of formulation process		X		A	482508-01
830.1670	Discussion on the formation of impurities		X		A	482508-01
830.1700	Preliminary analysis		X		A	482508-02
830.1750	Certified limits (158.350)	Standard certified limits	X		A	Revised CSF's 06-20-11
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	482508-02

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

8. Group **B:**

Guideline No.	**Study Title**	**Value or Qualitative Description**	**TRB's Assessment of Data**	**MRID Nos.**
830.6303	Physical State	Black granule	A	482508-06
830.6315	Flammability	>130 °C	A	482508-06
830.6316	Explodability	No explosive components	W	482508-06
830.7000	pH	6.0 @ 21 °C	A	482508-06
830.7300	Density	0.727 g/mL	A	482508-06

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the proposed end-use product and has concluded that:

1. The proposed revised CSF's for the basic formulation and alternate formulations (all dated 06-20-11) are acceptable.

2. The product chemistry data submitted corresponding to guideline 830.1600 (description of materials used to produce the product) are acceptable.

3. The product chemistry data submitted corresponding to guideline 830.1650 (description of the formulation process) are acceptable.

4. The product chemistry data submitted corresponding to guideline 830.1670 (discussion of the formation of impurities) are acceptable. [redacted] impurities originating with the technical grade aldicarb are considered to be of concern toxicologically, but they were not present at levels above 0.1% in the end product.

5. The product chemistry data submitted corresponding to guideline 830.1750 (certified limits) are acceptable.

6. The product chemistry data submitted corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.7000 (pH), 830.7100 (viscosity), 830.6314 (oxidation/reduction:chemical incompatibility), 830.6315 (flammability), 830.6316 (explodability waiver requested), 830.6319 (miscibility), and 830.7300 (density) are acceptable.

7. The registrant states that studies are ongoing to determine the storage stability (830.6317) and corrosion characteristics (830.6320) data for the product. The results of these studies should be provided upon completion. It is recommended that the observations should be made at 0, 3, 6, 9, and 12 month intervals.

8. The proposed product with File Symbol No. 87895-R was determined not to be substantially similar to the registered product (Reg. No. 264-330) from the product chemistry point of view for the following reasons:

- The density of the proposed product & cited products are significantly different (43.7 lbs/cu. ft. vs 63-71- lbs/cu. ft.).

- The source of the active ingredient (aldicarb) used in the proposed product & the cited product are not registered sources, consequently their impurity profiles could not be compared. The data submitted by AG Logic LLC does not adequately support "me-too" application. The Aventis Cropscience (acquired by Bayer Environmental Sciences in October 2001), the supplier of the unregistered technical aldicarb in the cited registered product has informed the Agency (letter dated 09-24-2002), that it has not authorized any me-too applicant to use or otherwise rely upon any aldicarb data currently on file with the Agency in support of a me-too application for a granular aldicarb product. See the full contents of the letter in confidential appendix page # 24.

ATTACHMENT 1

REPORT ON UN-REGISTERED TECHNICAL GRADE ALDICARB

DP BARCODE No.: 385364; **FILE SYMBOL No.**: 87895-R; **PRODUCT NAME**: MEYMIK 15G; **DECISION No.**: 440580; **PC Code(s)**: 098301 **ACTION CODE**: R330; **FOOD Use**: Yes

REPORT ON UN-REGISTERED TECHNICAL GRADE ALDICARB

SUMMARY OF FINDINGS:

1. The registrant submitted product chemistry data for technical grade aldicarb corresponding to guideline reference 830.1550 (product identity & composition) [MRID No. 482508-01 and 482508-02] to be produced for Ag Logic LLC [redacted] The registrant has proposed a nominal concentration of 96% for the active ingredient with upper and lower limits of 98.8% and 93.1%, respectively. The five-batch analysis data showed a maximum value of 96.4% and a minimum value of 95.6% for the active ingredient.

2. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) are acceptable [MRID No. 482508-01].

3. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) are acceptable [MRID No. 482508-01].

4. The product chemistry data submitted corresponding to guideline reference 830.1670 (discussion of the formation of impurities) are acceptable [MRID No. 482508-01]. [redacted] impurities originating with the technical grade aldicarb are considered to be of concern toxicologically [redacted]

5. The data submitted corresponding to the guideline reference 830.1700 (preliminary analysis) are acceptable [MRID No. 482508-02].

6. The data submitted corresponding to the guideline reference 830.1800 (enforcement analytical method) are acceptable [MRID No. 482508-02].

7. No data were submitted on the technical grade aldicarb corresponding to guideline 830 Series Subgroup B (physical-chemical properties).

CONCLUSIONS:

1). The product chemistry data submitted for guideline 830 Series group A are acceptable.

2). The end-use product MEYMIK 15G has one basic and four alternate formulations. The CSF for each formulation has an identical pg. 2 listing the specifications of technical grade aldicarb. The limits on the technical grade a.i. are within guideline limits, but the upper limits on all [redacted] impurities are above the guideline limits. [redacted] impurities originating with the technical grade aldicarb are considered to be of concern toxicologically [redacted]

3). Waiver is requested for guideline storage stability and corrosion characteristics testing, since technical grade aldicarb is not stored but used immediately to produce the end product.

4). The aldicarb technical contains following impurities of tox concern:

[redacted]

830.1550. Product identity & Composition: (MRID No. 482508-01)

Common Name: Aldicarb

Chemical name (CAS): 2-methyl-2-(methylthio)propanal *O*-[(methylamino)carbonyl]oxime

(IUPAC): 2-methyl-2-(methylthio)propionaldehyde *O*-methylcarbamoyloxime

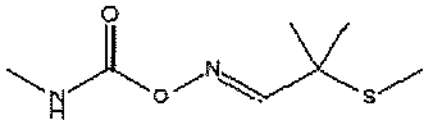
CAS No.: 116-06-3

PC Code No.: 098301

Empirical formula: $C_7H_{11}N_2O_2S$

Molecular Weight: 190.3

Structural formula:



830.1800. Enforcement analytical method: The enforcement analytical method to determine the content of active ingredient in the technical grade aldicarb is HPLC and LC-MS. Sample chromatograms were provided. The registrant provided the following details in MRID 482508-02:

1. METHODOLOGY

1.1 Equipment/Instruments

S. N°	Instruments	Model	Make / Supplier
1	Balance	GR-202	Adair dutt
2	HPLC	Agilent 1100 series	Agilent
3	LC-MS	Agilent 1100 series, binary pump with Agilent VWD/MSD	Agilent
4	FT-IR Spectrometer	Spectrum RX-1	Perkin Elmer

1.2 Solvents and Chemicals

S. N°	Name	Grade	Source
1	Water	Milli-Q	Milli-Q water system
2	Methanol	HPLC	Qualigens
3	Hydrochloric acid (concentrated)	AR	s.d. fine-chem ltd.
4	Sodium hydroxide	AR	Qualigens
5	Phenolphthalein indicator	AR	Qualigens
6	2-propanol	AR	Qualigens
7	Sodium carbonate	AR	Qualigens

1.3 Methodology for IR Analysis

1.3.1 Solid Sample Preparation for IR Analysis

A known quantity (2.0 mg approx) of each standard (Aldicarb and impurities viz., IMP-3, IMP-4 and IMP-5) and aldicarb technical sample was mixed with 100 mg (approx.) dried potassium bromide, separately. The mixture was finely ground using pestle and mortar and the fine powder was spread uniformly onto the mold. The pellet was prepared using a KBr press (pellet maker) by applying a pressure of 7 ton/in^2. The thin and transparent pellet was placed in a sample holder and sample holder along with the pellet was fixed into the sample slide of sample compartment of SPECTRUM RX-I FT-IR to record IR spectrum. The background spectrum was recorded before analysing the sample using a blank KBr pellet.

1.3.2 Liquid Sample Preparation for IR Analysis

A drop of liquid each standard (IMP-1 and IMP-2) was kept between two clean IR Cells. The cells were placed in the cell holder and screws were tightened carefully to form uniform and thin film of sample between the cells. The cell holder was fixed on sample slide of sample compartment. The IR spectrum was recorded using SPECTRUM RX 1 FT-IR. The background spectrum was recorded before analyzing the sample by using the blank IR cells.

All samples and background spectra were recorded using the following parameters:

Instrument	:	FT-IR Spectrometer (Spectrum RX-1)
Wave Number Range	:	400-4000 cm^{-1}
Resolution	:	4.0 cm^{-1}

1.4 Validation of HPLC Method

1.4.1 Characterization of Aldicarb Technical and Associated Impurities by LC-MS and Specificity by HPLC [IMP-1 to IMP-4]

1.4.1.1 Preparation of Standard Solution of Aldicarb and Associated Impurities for Characterization by LC-MS and Specificity by HPLC [IMP-1 to IMP-4]

Sample Details	Weight (mg) of Standard (W)	Purity (%)	Capacity (mL) of Volumetric Flask	Obtained Conc. (mg/L)	Identification of Standard Solution	Sol^n Taken (mL)	Capacity (mL) of Volumetric Flask	Obtained Conc. (mg/L)	Identification of Standard Solution
Aldicarb Standard	10.10	99.50	10	1004.95	A	1.0	10	100.50	F
IMP-1	10.79	96.11	10	1037.03	B	1.0	10	103.70	G
IMP-2	10.12	99.30	10	1004.92	C	1.0	10	100.49	H
IMP-3	10.42	99.50	10	1036.79	D	1.0	10	103.68	I
IMP-4	10.70	99.20	10	1061.44	E	1.0	10	106.14	J

Note: Volume was made upto the mark with methanol.

1.4.1.2 Preparation of Standard Mixture Solution of Aldicarb and Associated Impurities for Characterization by LC-MS and Specificity by HPLC

Identification of Standard Solution	Solution Taken (mL)	Capacity (mL) of Volumetric Flask	Volome made upto the mark with	Identification of Standard Solution
A	1.0	10	Methanol	Standard Mixture Solution M_t
B	1.0			
C	1.0			
D	1.0			
E	1.0			

1.4.2 Preparation of Sample Solution for Characterization by LC-MS and Specificity by HPLC

Batch N°	Weight (mg) of Sample	Capacity (mL) Volumetric Flask	Volume made upto the mark with
200811120132	20.79	10	Methanol
200811140135	20.52	10	
200811150136	20.35	10	
200811150137	20.61	10	
200811150138	20.30	10	

1.4.3 LC-MS Analytical Conditions

The above prepared **standard solution A** (Aldicarb), **standard solution B** [IMP-1], **standard solution C** [IMP-2], **standard solution D** [IMP-3], **standard solution E** [IMP-4], **standard mixture solution M_1**, methanol (solvent used for solution preparation) and sample solutions were injected onto LC-MS for characterization. The characterization of aldicarb and associated impurities were based on retention time, elution pattern and mass using following LC-MS parameters:

LC-MS Parameters

Instrument : LC-MSD SL
Column : X-Terra, C-8, [250 mm x 4.6 mm (i.d.), 5.0 µm particle size]
Wave Length : 205 nm
Mobile Phase : Methanol (25) : Milli-Q Water (75)
Flow Rate : 0.8 mL/minute
Injection Volume : 10.0 µL

MASS PARAMETERS

Mass Range : 50 to 500 m/z
Dry Gas Flow Rate : 10.0 L/minute
Dry Gas Temperature : 350 °C
Nebulizer Pressure : 50 psi
Fragmentor Voltage : 100 - 125 Volts (negative)
Quadra pole Temperature : 100 °C
Capillary Voltage : 4000 Volts (positive and negative)
Retention Time (Approx) : Aldicarb : 17.505 minutes
IMP-1 : 14.242 minutes
IMP-2 : 13.594 minutes
IMP-3 : 5.491 minutes
IMP-4 : 3.848 mioutes

1.4.4 HPLC Analytical Conditions

The above prepared **standard solution F** (Aldicarb), **standard solution G [IMP-1], standard solution H [IMP-2], standard solution I** [IMP-3], **standard solution J** [IMP-4], **standard mixture solution M_1,** methanol (solvent used for solution preparation) and sample solutions were injected onto HPLC for specificity. The specificity of aldicarb and associated impurities were based on retention time using following HPLC parameters:

Instrument	:	HPLC (Agilent 1100 series)
Column	:	X-Terra, C-8 [250 mm x 4.6 mm (I.d.), 5.0 µm particle size]
Wave length	:	205 nm
Mobile Phase	:	Methanol (22) : Milli-Q water (78)
Flow Rate	:	1.0 mL/minute
Injection Volume	:	20.0 µL
Retention Time (Approx)	:	Aldicarb : 13.076 minutes
		IMP-1 : 10.682 minutes
		IMP-2 : 10.068 minutes
		IMP-3 : 4.225 minutes
		IMP-4 : 3.002 minutes

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Pages 125-131 – *Manufacturing process information may be entitled to confidential treatment*

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Aventis CropScience

Aventis

EPA Correspondence No. 02-18A
September 24, 2002

Ms. Joanne Edwards
Registration Division (H7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Re: EPA Registration of Generic "Me-Too" Granular Aldicarb Products

Dear Ms. Edwards:

This letter is sent in anticipation that an application for a me-too registration for a granular aldicarb product may soon be made to the Registration Division of the Office of Pesticide Programs. Also, Aventis CropScience expects that the me-too applicant will cite the aldicarb and TEMIK® data on file with the EPA in support of such an application, including exposure data that pertain to the formulation of the aldicarb end-use products sold under the brandname, TEMIK®. In the alternative, the me-too applicant may cite the exposure data in the PHED database in support of this application.

In this context, the purpose of this letter is threefold. First, Aventis CropScience is informing EPA that Aventis has not authorized any me-too applicant to use or otherwise rely upon any aldicarb or TEMIK® data currently on file with the EPA in support of a me-too application for a granular aldicarb product. Second, for reasons that are set forth in this letter, Aventis is advising the EPA that it would be inconsistent with the requirements of FIFRA § 3(c)(7)(A) for the EPA to rely on the aldicarb and TEMIK® data in support of an application for a me-too registration of aldicarb. Because of differences in the composition of any anticipated me-too aldicarb product, its composition will not be substantially similar to the existing Aventis TEMIK® product, and the generic product will result in higher exposure to mixer/loader and applicators working with the product. Thirdly, Aventis is also advising EPA that, as explained in this letter, reliance on the PHED exposure data on part of the me-too applicant leads to the conclusion that handler exposure to the generic granular aldicarb presents unacceptable risk.

The TEMIK® Formulations

The current TEMIK® formulations have been designed to minimize exposure to aldicarb. Using state-of-the-art trade secret formulation technology, Aventis produces a granular formulation that essentially encapsulates the aldicarb and the gypsum carrier on which aldicarb is deposited. As this technology has been developed and applied over a period of 30 years it would not be an easy matter for a me-too applicant to develop such technology, and the EPA should be cautious about any representations to the contrary. Aventis has invested millions of dollars in perfecting the current trade secret TEMIK® formulations and has not shared the formulation process with anyone outside the company. Aventis is the only manufacturer using this formulation process.

Aventis CropScience · 2 TW Alexander Drive · Research Triangle Park NC 27709 · www.us.cropscience.aventis.com
Telephone (919) 549 2000

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The TEMIK® formulation technology incorporates a strict internal standard for dust content. This standard is [redacted] Dust analysis of TEMIK® 15G on file with the EPA measured dust levels in this formulation at [redacted] on average (TEMIK® Brand 15G Quality Control Data on Dust Control of Gypsum and Grit Formulations, MRID 45079706). In fact, the dust level for 99% of TEMIK® 15G production is less than [redacted] Most importantly, any TEMIK® 15G product with a dust content at or above [redacted] is recycled (remanufactured) and not sold. In contrast, dust analysis of a generic formulation of a 15% aldicarb granular product obtained on the global market from a producer of generic aldicarb showed dust levels of 0.18% and 0.37% of the formulation, a significantly higher amount of dust that will produce higher and unacceptable levels of exposure to aldicarb by mixer/loader and applicators of that product.

Furthermore, from dust analysis of MOCAP® 10G[1], an Aventis granular product containing the active ingredient ethoprop, Aventis has quantified the dust levels in this product at [redacted] on average. Thus the generic granular aldicarb formulation and the MOCAP® 10G formulation have similar dust levels which are both significantly higher than the TEMIK® 15G formulation. Both of these dusty formulations are equally unacceptable. Consequently, as part of the ethoprop reregistration agreement, Aventis volunteered to cancel the registration for MOCAP® 10G by December 31, 2001.

Exposure Data For Granular Products

Aventis has conducted a mixer/loader and applicator exposure study for TEMIK® 15G (MRID 43852501), which has been reviewed and accepted by EPA. This study shows that the dermal and inhalation exposure levels for TEMIK® 15G are approximately 100 times lower than typical granular formulations such as MOCAP® 10G and the granular formulations from which the limited PHED exposure data was generated.

Upon comparing the data from the MOCAP®10G worker exposure study (MRID 44984101) with the PHED granular worker exposure data, one finds almost identical dermal and inhalation exposure potential to the mixer/loader and applicators. Since the dust content of the generic granular aldicarb product has been demonstrated to be similar to the MOCAP® 10G product, the exposure potential for the MOCAP® 10G product would be the same for the generic aldicarb product. Although PHED data are not applicable to TEMIK® brand products, the PHED exposure data do apply to generic granular aldicarb formulations, which have a dust content similar to MOCAP® 10G. If exposure potential for a generic granular aldicarb formulation is calculated using PHED data, it is similar to the exposure calculated for MOCAP® 10G and approximately 100 times greater than TEMIK® 15G under comparable use conditions.

As previously noted, this fact leads to the conclusion that a generic granular aldicarb formulation, with an exposure profile calculated using the PHED exposure data, would present an unreasonable risk to the mixer/loaders and applicators of that formulation. As already mentioned, the worker exposure risk assessment to MOCAP® 10G was unacceptable and Aventis volunteered to cancel the registration.

It should be noted that the company experienced several overexposure incidents in the agricultural and specialty markets with the introduction of TEMIK® in the 1970's due to dust and other problems associated with the formulations. Significant efforts made to improve the formulations have lead to a dramatic reduction in dust in the current TEMIK® formulations. As a result of these changes, the incidents of worker overexposure to TEMIK® have been reduced to an average of less than one overexposure per year for the last 10 years. The opposite effect, an increase in incidents, would occur

[1] MOCAP® 10G is a granular product composed of the active ingredient ethoprop (an organophosphate insecticide) formulated on a clay substrate.

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should the EPA register a generic aldicarb formulation that is not formulated with technology comparable to the Aventis technology. This generic granular aldicarb formulation would almost certainly have a higher dust level, thus a greater exposure potential and thus a higher incidence of overexposure. Aventis is properly concerned that, in the event of such an increase in exposure incidents, users may not distinguish between TEMIK® products and the generic aldicarb product that produces higher exposure. It is important the EPA carefully consider whether the risk to the mixer/loader and applicators is unreasonable given the benefits from the use of such a generic aldicarb formulation and assure that these products are regulated on the basis of data that accurately represents the differing composition of the products.

The "Identical and Substantially Similar" Requirements of FIFRA § 3(c)(7)(A)

FIFRA § 3(c)(7)(A) requires EPA to determine whether a "me-too" pesticide is identical or substantially similar to a currently registered pesticide prior to approving the application for registration. FIFRA § 3(c)(7)(A) permits the EPA to "conditionally register . . . a pesticide if the Administrator determines that (i) the pesticide and proposed uses are identical or substantially similar to any currently registered pesticide and use thereof . . ." The EPA "will not approve the conditional registration of any pesticide under FIFRA § 3(c)(7)(A) unless the Agency has determined that the applicant's product and its proposed uses are identical or substantially similar to a currently registered pesticide and use . . ." See 40 C.F.R. § 152.113(b).

"Identicality"

To determine identicality prior to registration, the EPA compares the composition of the me-too pesticide to the composition of the currently registered pesticide (Standard Operating Procedure, Number: 3068.2, July 1, 1981). This SOP "calls for an initial examination of the composition of an applicant's product and then a comparison of the ingredients in the applicant's product with the ingredients in currently registered products". Applying this SOP, the EPA determines whether the me-too pesticide is the same or different from currently registered pesticides.

As noted, a generic aldicarb formulation would have a greater dust content than TEMIK® 15 G. This fact alone demonstrates that such a generic formulation would not be identical to TEMIK® 15G which is produced using trade secret formulation technology.

"Substantially Similar"

Absent identicality, a me-too pesticide can be registered only if it is substantially similar to the currently registered pesticide. The me-too achieves "substantially similar" status only when differences in composition do not significantly increase the risk of unreasonable adverse effects on the environment as shown by the results of an incremental risk assessment. See 40 C.F.R. § 152.113.

The greater dust content associated with a generic granular aldicarb formulation does, in fact, represent a difference in composition and requires that EPA determine whether this difference significantly increases the risk of unreasonable adverse effects on the environment. To answer this question, EPA must conduct an incremental risk assessment.

To conduct this incremeotal risk assessment, the EPA must have valid scientific data in its possession. In this instance, the applicant seeking registration of any generic granular aldicarb product must supply dust and exposure data on its generic aldicarb formulation provided by the me-too registrant. If it does not provide data on its specific formulation, it must rely on the PHED exposure data. Either method of fulfilling the data requirements would allow the EPA to determine whether the generic granular aldicarb formulation can be registered in compliance with the FIFRA§ 3(c)(7)(A).

DP BARCODE No.: 385364; **FILE SYMBOL** No.: 87895-R; **PRODUCT NAME**: MEYMIK 15G; **DECISION** No.: 440580; **PC Code(s)**: 098301 **ACTION CODE**: R330; **FOOD** Use: Yes

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The dust and exposure data on file with the EPA for TEMIK® 15G are not suitable for conducting an incremental risk assessment for a generic granular aldicarb product. The EPA has determined from the TEMIK® 15G exposure data (MRID 43852501) that the use of TEMIK® 15G does not generally pose unreasonable adverse effects to the mixer/loader and applicator. The risk analysis that led to this determination can not be applied to a generic aldicarb formulation, which has a greater dust content than that of TEMIK® 15G, and therefore a greater exposure potential. This greater exposure potential presents
a significantly different risk profile for such a generic aldicarb formulation than for TEMIK® 15G. Given this point, the use of the TEMIK® 15G dust and exposure data to conduct such an incremental risk assessment would be an invalid scientific exercise and not satisfy the requirements of FIFRA§ 3(c)17)(A).

Conclusion

If an applicant does apply for registration of a generic granular aldicarb product, the EPA must require the applicant to present data on the dust content of its granular formulation. Should the dust content of the generic granular aldicarb product be significantly greater than that of the TEMIK® 15G formulation, the EPA must require exposure data for mixer/loader and applicator. This data is necessary for the EPA to perform an incremental risk analysis to determine whether the generic aldicarb formulation significantly increases the risk of any unreasonable adverse effect to workers or to the environment. Such an incremental risk analysis would be necessary for compliance with the registration requirements of FIFRA § 3(c)(7)(A), the section of FIFRA under which the generic aldicarb formulation would be registered. The aldicarb dust (MRID 45079706) and exposure data (MRID 43852501) cannot be used for this purpose because of the lack of substantial similarity between the TEMIK®15G and the generic granular aldicarb formulation.

Given the potentially significant toxicological and environmental consequences resulting from the registration of a generic me-too product that is not comparable to TEMIK®, the EPA must conduct an incremental risk analysis using valid scientific studies submitted by the generic me-too registrant. Such conduct is required to ensure that the generic me-too product does not pose an unreasonable risk to workers or the environment. If the EPA registers a generic me-too granular aldicarb product without first making this detailed assessment it is likely that there will be a significant increase in incidents of overexposure to workers using the generic me-too product and that the reputation of both Aventis and the EPA will be negatively impacted because the public will not distinguish between TEMIK®15G and a generic aldicarb product. In order to avoid confusing the public and to meet its statutory obligations for registering generic pesticides, EPA must assure that an applicant to register generic aldicarb submits data on its own formulation to the extent that its product is not substantially similar to existing aldicarb products.

I can be reached at 919-549-2870. Please contact me if you have any questions regarding this letter.

Sincerely,

Larry R. Hodges, Ph.D.
Registration Manager

cc: Meredith Laws
Jeffrey Dawson
Jeffrey Evans
John Redden

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 21, 2011

MEMORANDUM

Subject:	Name of Pesticide Product:	MEYMIK 15G
	EPA Reg. No. /File Symbol:	87895-R
	DP Barcode:	DP 385365
	Decision No.:	440580
	Action Code:	R330
	PC Code:	098301 (Aldicarb: 15%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
June-21-2011

M Hawkins
Team Leader, Toxicology

To: Autumn Metzger/John Hebert RM 07
Insecticide-Rodenticide Branch
Registration Division (7505P)

Registrant: AG LOGIC LLC

FORMULATION FROM LABEL:

Active Ingredient:	by wt.
098301 Aldicarb	15.0%
Other Ingredient(s):	85.0%
TOTAL	100.0%

ACTION REQUESTED: The Risk Manager requests:

"Please review the following data submission to support this new product. Enclosed are: cover letter from company, CSFs, data matrix (pages citing acute tox data only) and data."

BACKGROUND:

The material received for review includes a set of 6 acute toxicity studies (all in one volume with MRID 48250807), a cover letter from the registrant (dated September 29, 2010), a data matrix (which indicates the registrant is citing the 6 submitted acute toxicity studies to satisfy these data requirements) and a basic CSF and 3 alternate CSFs.

COMMENTS AND RECOMMENDATIONS:

1. Five of the 6 acute toxicity studies have been classified as acceptable. The acute inhalation toxicity study (pp. 61-100, MRID 48250807) has been classified as unacceptable, and cannot be used to support the registration of 87895-R. This reviewer has a number of concerns regarding this study, particularly that the test animals may have been exposed to considerably less than the reported analytical values of test substance.

2. Although the inhalation study has been classified as unacceptable, the proposed product can be registered with assignment to EPA Toxicity Category I for inhalation toxicity.

3. The following is the acute toxicity profile for EPA File Symbol 87895-R (MEYMIK 15G), based on the results of the acute toxicity studies and the assignment to Toxicity Category I by the inhalation exposure route:

Acute oral toxicity	I	Acceptable	Pp. 8-29; MRID 48250807
Acute dermal toxicity	I	Acceptable	Pp. 30-60; MRID 48250807
Acute inhalation toxicity	I	Waived (with assignment to Tox. Cat. I)	
Primary eye irritation	IV	Acceptable	Pp. 101-119 MRID 48250807
Primary dermal irritation	IV	Acceptable	Pp. 120-138 MRID 48250807
Dermal sensitization	Negative	Acceptable	Pp. 139-162 MRID 48250807

4. Based on the acute toxicity profile above, and taking into consideration the proposed uses specified on the label and information in the CSF, the following would be the precautionary and first aid labeling for EPA File Symbol 87895-R (MEYMIK 15G) as obtained from the Label Review System:

PRODUCT ID #: **087895-00001**

PRODUCT NAME: **MEYMIK 15G**

PRECAUTIONARY STATEMENTS

SIGNAL WORD: **DANGER** **POISON** ☠

Hazards to Humans and Domestic Animals:

Fatal if absorbed through skin. Fatal if inhaled. Fatal if swallowed. Do not breathe dust. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear coveralls worn over long-sleeved shirt and long pants, socks, chemical-resistant footwear, and gloves. Remove and wash contaminated clothing before reuse.

First Aid:

If on skin:
-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment advice.

If inhaled:
-Move the person to fresh air.
-If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
-Call a poison control center or doctor for further treatment advice.

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a Note to Physician which addresses the presence of a cholinesterase inhibitor and category I Acute Dermal Toxicity, Acute Inhalation Toxicity, Acute Oral Toxicity. The following statements are suggested types of information that may be included, if applicable:
- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

5. The basic and alternate CSFs (dated September 23, 2010) for 87895-R should also be reviewed and accepted by the TRB Chemistry Team.

Reviewer: Byron T. Backus, Ph.D. **Date:** June 17, 2011
Risk Manager (EPA): 07

STUDY TYPE: Acute Oral Toxicity – Rat; OPPTS 870.1100; OECD 425

TEST MATERIAL: ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb.

CITATION: Parodi, F. Acute Oral Toxicity of Aldicarb 15% WG in Rats (*Rattus norvegicus).* Study Number: **BIDI** 9 – 4039. Microquim S.A., Av. Triunvirato 3447 (1427), Buenos Aires, Argentina. May 20, 2010. Pp. 8-29, MRID 48250807.

SPONSOR: ENVIRO AG CONSULTING GROUP / MEY CORPORATION

EXECUTIVE SUMMARY: In an acute oral toxicity study (pp. 8-29, MRID 4825087), fasted (overnight) young adult female Sprague-Dawley rats (age: 8-12 weeks; weights: 203-216 g at dosing; source: Facultad de Ciencias Veterinarias, Universidad de Buenos Aires) were orally gavaged with the test material as a suspension in corn using the up-and-down procedure. The animals were dosed using a constant dose volume of 1 mL/100 g body weight. The dosages (and corresponding concentrations in corn oil) were 175 mg/kg (1.75% w/v), 55 mg/kg (0.55% w/v), and 17.5 mg/kg (0.175% w/v). The initial animal was dosed at 175 mg/kg, and when this animal died the next animal was dosed at 55 mg/kg.

The one female that was dosed at 175 mg/kg was dead at 2 hours after dosage. All 3 females dosed at 55 mg/kg were dead at 4 hours after dosage. All 3 females dosed at 17.5 mg/kg survived, but showed signs of toxicity (lethargy, slight "xifosis" [presumably kyphosis, or curvature of the back], piloerection and chromodacryorrhea, with recovery by day 7. The three females dosed at 17.5 mg/kg all gained weight in the period from Day 0 to 7 and again from Day 7 to 14. At necropsy, there were no gross lesions.

Female rat LD_{50} = 29.57 mg/kg (approximate 95% confidence limits: 17.5-55 mgf/kg).

Based on the acute oral LD_{50} = 29.57 mg/kg, Aldicarb 15% WG, a granular product containing 15.3% Aldicarb, is in EPA Toxicity Category I by oral exposure.

COMPLIANCE: Signed and dated GLP, Quality Assurance and [No] Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Date/Time: Friday, June 17, 2011, 3:58:06 PM
Data file name: work.dat
Last modified: 6/17/2011 3:58:04 PM

Test/Substance: Aldicarb 15% WG
Test type: Main Test
Limit dose (mg/kg): 2000
Assumed LD50 (mg/kg): Default
Assumed sigma (mg/kg): 0.5

Recommended dose progression: 2000, 550, 175, 55, 17.5, 5.5, 1.75

DATA:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
1	1	175	X	X
2	2	55	X	X
3	3	17.5	O	O
4	4	55	X	X
5	5	17.5	O	O
6	6	55	X	X
7	7	17.5	O	O

(X = Died, O = Survived)

Dose Recommendation: The main test is complete.

Stopping criteria met: 5 reversals in 6 tests.

SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
17.5	3	0	3
55	0	3	3
175	0	1	1
All Doses	3	4	7

Statistical Estimate based on long term outcomes:

Estimated LD50 = 29.57 (Based on an assumed sigma of 0.5).
Approximate 95% confidence interval is 17.5 to 55.

A. **Mortality:** The one female dosed at 175 mg/kg was dead at 2 hours after dosage. All 3 females dosed at 55 mg/kg were dead at 4 hours after dosage. All 3 females dosed at 17.5 mg/kg survived.

B. **Clinical observations:** At 175 mg/kg predeath signs of toxicity included tremors followed by convulsions and diarrhea. At 55 mg/kg there were tremors, siallorrea and piloerection, followed by death. At 17.5 mg/kg all 3 females showed signs of toxicity which included lethargy, slight "xifosis" [presumably kyphosis, or curvature of the back], piloerection and chromodacryorrhea, with recovery by day 7. The three females dosed at 17.5 mg/kg allk gained weight in the period from Day 0 to 7 and again from Day 7 to 14.

C. **Gross necropsy:** There were no gross lesions.

D. **Reviewer's conclusions:** Based on the acute oral LD_{50} = 29.57 mg/kg, Aldicarb 15% WG, a granular product containing 15.3% Aldicarb, is in EPA Toxicity Category I by oral exposure.

Reviewer: Byron T. Backus Date: June 20, 2011
Risk Manager (EPA): 07

STUDY TYPE: Acute Dermal Toxicity – Rat; OPPTS 870.1200; OECD 402

TEST MATERIAL: ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb.

CITATION: Parodi, F. Acute Dermal Toxicity of Aldicarb 15% WG in Rats (*Rattus norvegicus)*. Study Number: BIDI 9 – 4040. Microquim S.A., Av. Triunvirato 3447 (1427), Buenos Aires, Argentina. May 20, 2010. Pp. 30-60, MRID 48250807.

SPONSOR: ENVIRO AG CONSULTING GROUP / MEY CORPORATION

EXECUTIVE SUMMARY: In an acute dermal toxicity study (pp. 30-60, MRID 48250807), groups of five male and five female young adult Sprague-Dawley Crl:CD®(SD) IGS-BR rats (age: 8-12 weeks; weights: males: 205-228 g; females: 203-223 g: source: Facultad de Ciencias Veterinarias, Universidad de Buenos Aires, Av. Chorroarin 280, C1427CWO, Buenos Aires, Argentina) were dermally exposed for 24 hours to 50, 75, 100, 250 or 500 mg/kg of Aldicarb 15% WG (containing 15.3% active ingredient) in corn oil; the respective concentrations of test material in corn oil were 0.5%, 0.75%, 1%, 2.5% and 5% w/v. The test material-solvent mixture was uniformly applied at the appropriate dose to a shaved area on the dorsal trunk. Following the application, a porous bandage (presumably covering the application site) was wrapped around each animal and was kept in place with non-irritant tape. From p. 41 of MRID 48250807: "Animals were not entirely immobilized." At the end of the exposure period residues of the test material were removed with water. The rats were observed for 14 days.

All rats survived dosage at 50 mg/kg, although all had lethargy at 1 hour after administration continuing in some of the animals through day 2. No toxicity was observed from day 3 through day 14. At 75 mg/kg, one female died (or was found dead) on day 1; all rats showed signs of toxicity, which included lethargy, piloerection and chromodacryorrhea, with recovery in all survivors by day 3. At 100 mg/kg, 3/5 females and 1/5 males died (or were found dead) on day 1; all other rats survived. Signs of toxicity consisted of lethargy and slight tremors, with recovery in all survivors by day 5. At 250 mg/kg, 3/5 females and 4/5 males died (or were found dead) on day 1; all other rats survived. Signs of toxicity (which included tremors, sialorrea, "xifosis" [presumably kyphosis] and chromodacryorrhea persisted up to day 6 in one survivor. At 500 mg/kg, 5/5 females and 5/5 males died (or were found dead) on day 1; signs of toxicity included tremors and sialorrea.

All survivors gained bodyweight from day 0 to 7 and again from day 7 to 14.

Dermal LD_{50} Males: not reported
Dermal LD_{50} Females: not reported
Dermal LD_{50} Combined = 149.87 mg/kg; from p. 43 of MRID 48250807: Lower limit of the confidence limit (p: 0.05): 111.99; Upper limit of the confidence interval (p:0.05): 215.24.

Based on the acute dermal LD_{50} = 149.87 mg/kg, Aldicarb 15% WG (containing 15.3% active ingredient), is in EPA Toxicity Category I for dermal toxicity.

This study is classified as acceptable. It does satisfy the guideline requirements for an acute dermal study (OPPTS 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and [No] Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
50	0/5	0/5	0/10
75	0/5	1/5	1/10
100	1/5	3/5	4/5
250	4/5	3/5	7/10
500	5/5	5/5	10/10

A. **Mortality:** All rats survived dosage at 50 mg/kg. At 75 mg/kg, one female died (or was found dead) on day 1. At 100 mg/kg, 3/5 females and 1/5 males died (or were found dead) on day 1; all other rats survived. At 250 mg/kg, 3/5 females and 4/5 males died (or were found dead) on day 1; all other rats survived. At 500 mg/kg, 5/5 females and 5/5 males died (or were found dead) on day 1.

B. **Clinical observations:** All animals showed signs of toxicity, which included lethargy (only sign observed at 50 mg/kg), piloerection, chromodacryorrhea, tremors, sialorrea, and "xifosis" [presumably kyphosis, or curvature of the back].

C. **Gross necropsy:** There were no gross lesions observed in either the rats which died on test or those which were sacrificed at the end of the 14-day observation period.

D. **Reviewer's conclusions:** The combined sex acute dermal LD_{50} is 149.87 mg/kg bw. Aldicarb 15% WG (containing 15.3% active ingredient), is in EPA Toxicity Category I for dermal toxicity.

Reviewer: Byron T. Backus, Ph.D. **Date:** June 20, 2011
Risk Manager (EPA): 07

STUDY TYPE: Acute Inhalation Toxicity – Rat; OPPTS 870.1300; OECD 403

TEST MATERIAL: ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb.

CITATION: Parodi, F. Acute Inhalation Toxicity of Aldicarb 15% WG in Rats (*Rattus norvegicus)*. Study Number: BIDI 9 – 4041. ID: 50606. Microquim S.A., Av. Triunvirato 3447 (I427), Buenos Aires, Argentina. May 20, 2010. Pp. 61-100, MRID 48250807.

SPONSOR: ENVIRO AG CONSULTING GROUP / MEY CORPORATION

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (pp. 61-100, MRID 48250807), groups of five male and five female Sprague-Dawley Crl:CD®(SD) IGS-BR rats (age: "young adult"; weights: males: 203-218 g; females: 206-220 g: source: Facultad de Ciencias Veterinarias, Universidad de Buenos Aires, Av. Chorroarin 280, C1427CWO, Buenos Aires, Argentina) were exposed (nose-only) for 4 hours to nominal concentrations of 0.05, 0.1, 0.2 and 0.4 mg Aldicarb 15%/L of air [the corresponding analytical concentrations were: 0.047, 0.089, 0.18 and 0.39 mg/L]. Prior to testing, the test material was pulverized ("passed through the mortar") to get a powder. The rats were observed for 14 days after exposure.

At 0.047 mg/L all rats survived, although all showed signs of toxicity (lethargy and piloerection) through day 3; no toxicity was observed on days 4 through 14. At 0.089 mg/L, 1/5 males and 2/5 females died (or were found dead) on day 2; signs of toxicity were lethargy, piloerection, incoordination and sialorrea [sialorrhea = drooling, excessive salivation]; all surviving rats were clear of toxicity by day 8. At 0.18 mg/L, 2/5 males and 4/5 females died (or were found dead) on days 1 or 2; signs of toxicity were prostration, lethargy and piloerection; these had cleared in the survivors by day 9. At 0.39 mg/L all (5/5 males, 5/5 females) rats died, with 9 of the deaths occurring at 4 hours (the end of the exposure period?). Predeath signs of toxicity included prostration, lethargy and piloerection.

All survivors gained weight in the period from day 0 to 7 and again from day 7 to 14.

No gross lesions were observed at necropsy in either the rats which died on test or those which survived to the end of the 14-day observation period.

The median lethal dose is reported as 0.14 mg/L (analytical concentration) on p. 69 of MRID 48250807.

However, this reviewer has several concerns regarding the results of this study, as indicated below.

The analytical concentrations range from 89 to 97.5% of the nominal values. This is unusual as it has been our experience that the analytical concentration for an aerosol formulation is usually at least one order of magnitude below (or one tenth) the nominal value.

If this reviewer has correctly interpreted the schematic diagrams on pages 78 and 79 of MRID 48250807, the test material entered through the top of the chamber, and exited through the bottom. It was the material that had exited through the bottom of the chamber that was analyzed. The 870.1300 Acute Inhalation Toxicity Guidelines specify that: "The actual concentrations of the test substance should be measured in the breathing zone," and this does not appear to have been done. It is possible then that the test subjects may have been exposed to considerably less than the reported analytical values of test substance.

According to the report, the size of the aerosol particles was determined through measurement of particles captured in vaseline. This is an older methodology (this reviewer has found references to a similar measurement process dating from the 1930s); currently, most particle size data in inhalation studies is obtained using a cascade impactor and/or filters. It is important to note that what is reported is the MAD (Mean or Median Aerodynamic Diameter), rather than the MMAD (Mean Mass Aerodynamic Diameter). The MAD value would generally be less than the MMAD value. While the 870.1300 Acute Inhalation Study Guidelines do not specify a methodology for determining particle size, the statement is made that: "The MMAD particle size range should be between 1-4 µm..."

Because of the concerns indicated above, particularly that the test animals may have been exposed to considerably less than the reported analytical values of test substance, this study is classified as unacceptable. It does **not** satisfy the guideline requirements for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and [No] Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Nominal Conc. (mg/L)	Gravimetric Concentration (mg/L)	MAD[a] µm	Mean GSD	Mortality/Number Tested		
				Males	Females	Combined
0.05	0.047	3.62	n.r.	0/5	0/5	0/10
0.1	0.089	3.68	n.r.	1/5	2/5	3/10
0.2	0.18	3.53	n.r.	2/5	4/5	6/10
0.4	0.39	3.72	n.r.	5/5	5/5	10/10

[a]MAD = Mean (or Median) Aerodynamic Diameter; not MMAD = Mean Mass Aerodynamic Diameter
n.r. = not reported

Test atmosphere / Chamber description: From p. 72 of MRID 48250807: "The exposure was performed in a 2.7L "only nasal" chamber… The mixture of air and test substance was generated with [a] powder aerosol generator connected to the inhalation chamber by plastic tubing, to generate 15 air changes per hour. The air extracted from the chamber went through a treatment system that consisted on [of?] making it bubble in a (50:50) Acetonitrile water solution…" From the diagrams, rats were housed in individual tubes providing nose-only exposure to the chamber atmosphere.

Mean Formulation Conc. (mg/L):	0.047	0.089	0.18	0.39
Chamber Volume (L):	2.7	2.7	2.7	2.7
Mean Airflow (L/min):	0.675	0.675	0.675	0.675
Range of Temperature (° C):	20-22	20-22	20-21	21-22
Range of Relative Humidity (%):	65-74	65-75	65-75	65-76
Time to t_{99} equilibrium (minutes):	40	35	40	30

Test atmosphere concentration: From p. 73-74 of MRID 48250807: "The nominal concentration of the test substance was calculated for the exposure dividing the total amount of the aerosolized test substance (mg) by the total amount of air that flowed through the chamber…" From p. 93 of MRID 48250807: "For the substance collection, the air extractor from the chamber was bubbled at different times set in advance, in an H_2O: ACN [50% H_2O: 50% Acetonitrile] solution, retaining in this way the substance in that solution." The amount of captured aldicarb was determined using HPLC – FLD.

Particle size determination: From p. 73 of MRID 48250807: "The size of the aerosol particles was determined twice during exposure through drop measurement, which is obtained by emulsifying the cloud generated in the inhalation chamber, in vaseline." For each determination, a drop of vaseline was placed on a microscope slide, which was examined using a microscope with a 100X immersion objective, and the diameters of 200 [randomly selected?] particles were measured.

A. **Mortality:** At 0.047 mg/L all rats survived. At 0.089 mg/L, 1/5 males and 2/5 females died (or were found dead) on day 2. At 0.18 mg/L, 2/5 males and 4/5 females died. At 0.39 mg/L all (5/5 males, 5/5 females) rats died, with 9 of the deaths occurring at 4 hours (the end of the exposure period?).

B. **Clinical observations:** All rats showed signs of toxicity, which included lethargy, piloerection, incoordination, sialorrea [sialorrhea = drooling, excessive salivation] and prostration, consistent with cholinesterase inhibition.

C. **Gross necropsy:** There were no gross lesions.

D. **Reviewer's conclusions:** The median lethal dose is reported as 0.14 mg/L on p. 69 of MRID 48250807. However, there are a number of concerns, particularly that the test animals may have actually been exposed to considerably less than the measured concentrations. This study is classified as unacceptable, and cannot be used to satisfy the acute inhalation toxicity study requirement (OPPTS 870.1300, OECD 403) for the registration of ALDICARB 15% WG.

Reviewer: Byron T. Backus, Ph.D. **Date:** June 21, 2011
Risk Manager (EPA): 07

STUDY TYPE: Primary Eye Irritation – Rabbit; OPPTS 870.2400; OECD 405

TEST MATERIAL: ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb, pH = 6.1 (for a 1% aqueous solution).

CITATION: Lope, N. Eye Irritation/Corrosion Effects in Rabbits (*Oryctolagus cuniculus*) of Aldicarb 15% WG. Study Number: BIDI 9 – 4043. ID: 50606. Microquim S.A., Av. Triunvirato 3447 (1427), Buenos Aires, Argentina. May 20, 2010. Pp. 101-119, MRID 48250807.

SPONSOR: ENVIRO AG CONSULTING GROUP / MEY CORPORATION

EXECUTIVE SUMMARY: In a primary eye irritation study (pp. 101-119, MRID 48250807), 0.1 g of ALDICARB 15% WG, a granular product containing 15.3% Aldicarb, was instilled into one eye of each of 3 young adult male albino rabbits (weights: 2640-2780 g; source: Cabaña La Pureza, Zelarrayan 5089 – Pdo. Gral. Rodriguez. Pcia. Buenos Aires). The eyes were examined and scored for irritation at 1, 24, 48 and 72 hours after instillation.

The rabbits had tachycardia for 4 hours after instillation. There was no corneal opacity or iritis. At one hour, all 3 eyes scored "4" for conjunctival redness [note: the maximum score for redness in the OPPTS grading system is "3"] and "3" for secretion [or discharge]. At 24, 48 and 72 hours none of the eyes was positive for irritation (and all scores were zero). The Maximum Mean Irritation Score was 14.0, observed at 1 hour after treatment [note: since the maximum score for redness in the OPPTS grading system is 3 the Maximum Mean Total Score (MMTS) would be 12.0].

In this study, there was no corneal opacity or iritis, and none of the eyes was positive for irritation at 24 hours or subsequently. ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb, is in EPA Toxicity Category IV for eye irritation.

This study is classified as acceptable. It does satisfy the guideline requirements for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Observations	Number of eyes positive/Number treated			
	Hours			
	1	24	48	72
Corneal Opacity	0/3	0/3	0/3	0/3
Iritis	0/3	0/3	0/3	0/3
Conjunctivae				
Redness*	3/3	0/3	0/3	0/3
Chemosis*	0/3	0/3	0/3	0/3
Discharge**	0/3	0/3	0/3	0/3

* Score of 2 or more required to be considered "positive"
** Discharge does not indicate a positive effect according to the grading scale

A. **Observations:** The rabbits had tachycardia for 4 hours after instillation. There was no corneal opacity or iritis. At one hour, all 3 eyes scored "4" for conjunctival redness [note: the maximum score for redness in the OPPTS grading system is "3"] and "3" for secretion [or discharge]. At 24, 48 and 72 hours none of the eyes was positive for irritation (and all scores were zero). The Maximum Mean Irritation Score was 14.0, observed at 1 hour after treatment [note: since the maximum score for redness in the OPPTS grading system is 3 the Maximum Mean Total Score (MMTS) would be 12.0].

B. **Results:** The Maximum Mean Total Score (MMTS) as calculated by this reviewer was 12.0 at 1 hour.

C. **Reviewer's conclusions:** In this study, there was no corneal opacity or iritis, and none of the eyes was positive for irritation at 24 hours or subsequently. ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb, is in EPA Toxicity Category IV for eye irritation.

STUDY TYPE: Primary Dermal Irritation – Rabbit; OPPTS 870.2500; OECD 404

TEST MATERIAL: ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb, pH = 6.2 (for a 1% aqueous solution).

CITATION: Lope, N. Acute Dermal Irritation/Corrosion Effects in Rabbits (*Oryctolagus cuniculus*) of Aldicarb 15% WG. Study Number: BIDI 9 – 4042. ID: 50606. Microquim S.A., Av. Triunvirato 3447 (1427), Buenos Aires, Argentina. May 20, 2010. Pp. 120-138, MRID 48250807.

SPONSOR: ENVIRO AG CONSULTING GROUP / MEY CORPORATION

EXECUTIVE SUMMARY: In a primary dermal irritation study (pp. 120-138, MRID 48250807) 0.5 g of ALDICARB 15% WG, a granular product containing 15.3% Aldicarb (which had been ground into a fine powder), was applied to a semi-occlusive gauze patch which in turn was placed on a 6 cm^2 dermal site on each of three young adult male rabbits (weights: 3100-3200 g; source: Cabaña La Pureza, Zelarrayan 5089 – Pdo. Gral. Rodriguez. Pcia. Buenos Aires), with 4-hour exposure. The vehicle used (for wetting the test material?) was corn oil. The sites were examined and scored for irritation at 1, 24, 48 and 72 hours after patch removal.

There was no indication of systemic toxicity. At 1 hour one site scored "1" for edema and zero for erythema; the other two sites scored zero for both edema and erythema. At 24, 48 and 72 hours all three sites scored zero for both edema and erythema. The Primary Dermal Irritation Index (PDII) = 0.08, and the mean irritation score at 72 hours = 0.00.

In this study, ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb caused very slight irritation (PDII = 0.083) following 4-hour exposure. The mean irritation score at 72 hours was 0.00. The test material is classified in EPA Toxicity Category IV for primary dermal irritation.

This study is classified as acceptable. It does satisfy the guideline requirements for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance and [No] Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Animal Number	Sex	Hours			
		1	24	48	72
1	Male	0/1	0/0	0/0	0/0
2	Male	0/0	0/0	0/0	0/0
3	Male	0/0	0/0	0/0	0/0
Severity of Irritation: Mean Score		0.00/0.33	0.00/0.00	0.00/0.00	0.00/0.00

[a] erythema/edema.

A. **Observations:** There was no indication of systemic toxicity. At 1 hour one site scored "1" for edema and zero for erythema; the other two sites scored zero for both edema and erythema. At 24, 48 and 72 hours all three sites scored zero for both edema and erythema.

B. **Results:** The Primary Dermal Irritation Index (PDII) = 0.08, and the mean irritation score at 72 hours = 0.00.

C. **Reviewer's conclusions:** In this study, ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb caused very slight irritation (PDII = 0.083) following 4-hour exposure. The mean irritation score at 72 hours was 0.00. The test material is classified in EPA Toxicity Category IV for primary dermal irritation.

Reviewer: Byron T. Backus, Ph.D. **Date:** June 21, 2011
Risk Manager (EPA): 07

STUDY TYPE: Dermal Sensitization – Guinea Pig; OPPTS 870.2600; OECD 406

TEST MATERIAL: ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb.

CITATION: Parodi, F. Skin Sensitization in Guinea Pigs (*Cavia porcellus*) of Aldicarb 15% WG Buehler Test. Study Number: BIDI 9 – 4044. ID: 50606. Microquim S.A., Av. Triunvirato 3447 (1427), Buenos Aires, Argentina. May 20, 2010. Pp. 139-162, MRID 48250807.

SPONSOR: ENVIRO AG CONSULTING GROUP / MEY CORPORATION

EXECUTIVE SUMMARY: In a dermal sensitization study (pp. 139-162, MRID 48250807) with ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb, a group of 20 (10M & 10F) young adult albino guinea pigs (weights: males: 325-345 g; females: 315-340 g; source: Instituto Biológico Argentino) were each dermally exposed on a once-a-week basis (days 0, 7 and 14) to 2-cm x 4-cm filter papers loaded with approximately 0.5 g of test material homogenized with corn oil. The filter papers were applied to a shaved area on the left flank and were held in contact with the skin for 6 hours by a hypoallergenic adhesive bandage.

A control group of 10 (5M & 5F) guinea pigs was similarly exposed to filter papers containing ~0.5 mL corn oil.

On Day 28 all 30 guinea pigs were dermally exposed (on a shaved area on the right flank) to 2-cm x 4-cm filter papers containing 0.5 g of test material homogenized with corn oil. Exposure was for 6 hours, and the exposure sites were evaluated and scored at 24 and 48 hours.

There was no irritation (all scores zero) at both 24 and 48 hours in all 30 guinea pigs.

The report includes the summary results of a positive control assay (for the period January-June 2010) with 100% Benzocaine. The results (10/20 guinea pigs with a positive response at 24 and/or 48 hours) were appropriate.

Based on the results of this study, ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb, is not a dermal sensitizer.

This study is classified as Acceptable. It does satisfy the guideline requirements for a dermal sensitization study (OPPTS 870.2600; OECD 406) in the guinea pig.

COMPLIANCE: Signed and dated GLP, Quality Assurance and [No] Data Confidentiality statements were provided.

PROCEDURE:

A. **Induction:** Twenty (10M & 10F) young adult albino guinea pigs were each dermally exposed on a once-a-week basis (days 0, 7 and 14) to 2-cm x 4-cm filter papers loaded with approximately 0.5 g of test material homogenized with corn oil. The filter papers were applied to a shaved area on the left flank and were held in contact with the skin for 6 hours by a hypoallergenic adhesive bandage.

B. **Challenge treatment:** On Day 28 the twenty guinea pigs were dermally exposed (on a shaved area on the right flank) to 2-cm x 4-cm filter papers containing 0.5 g of test material homogenized with corn oil. Exposure was for 6 hours, and the exposure sites were evaluated and scored at 24 and 48 hours.

C. **Negative controls:** During the induction period, a control group of 10 (5M & 5F) guinea pigs was exposed (on the left flank) on days 0, 7 and 14 to filter papers containing ~0.5 mL corn oil. On day 28 the guinea pigs of this group were dermally exposed (on a shaved area of the right flank) for 6 hours to 2 x 4-cm filter papers containg 0.5 g of test material homogenized with corn oil.

RESULTS and DISCUSSION:

A. **Reactions and durations:** Following challenge, all guinea pigs scored zero at both 24 and 48 hours.

B. **Positive control:** The report includes the summary results of a positive control assay (for the period January-June 2010) with 100% Benzocaine. The results (10/20 guinea pigs with a positive response at 24 and/or 48 hours) were appropriate.

C. **Reviewer's conclusions:** Based on the results of this study, ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb, is not a dermal sensitizer.

1. **DP BARCODE:** 385365
2. **PC CODE:** 098301 (Aldicarb)
3. **CURRENT DATE:** June 21, 2011
4. **TEST MATERIAL:** ALDICARB 15% WG, Batch No. 20081201001, a granular product containing 15.3% Aldicarb.

Study/Species/Lab Study # / Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Microquim S.A., Buenos Aires BIDI 9-4039 May 20, 2010	Pp. 8-29. 48250807	Female rat LD_{50} = 29.57 mg/kg	I	A
Acute dermal toxicity/rat Microquim S.A., Buenos Aires BIDI 9-4040 May 20, 2010	Pp. 30-60 48250807	LD_{50} Males = not reported LD_{50} Females = not reported LD_{50} Combined = 149.87 mg/kg bw	I	A
Acute inhalation toxicity/rat Microquim S.A., Buenos Aires BIDI 9-4041 May 20, 2010	Pp. 61-100 48250807	Median lethal dose reported as 0.14 mg/L. Rats may have been exposed to considerably less than the reported analytical values of test material.	?	U
Primary eye irritation/rabbit Microquim S.A., Buenos Aires BIDI 9-4043 May 20, 2010	Pp. 101-119 48250807	Rabbits had tachycardia for 4 hours after instillation. None of eyes was positive for irritation at 24 hrs or subsequently.	IV	A
Primary dermal irritation/rabbit Microquim S.A., Buenos Aires BIDI 9-4042 May 20, 2010	Pp. 120-138 48250807	PDII = 0.08 Mean irritation score at 72 hrs = 0.00	IV	A
Dermal sensitization/guinea pig Microquim S.A., Buenos Aires BIDI 9-4044 May 20, 2010	Pp. 139-162 48250807	Buehler: Negative	Neg.	A

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, W = Waived

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 5, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-440580
EPA File Symbol or Registration Number: 87895-R
Product Name: MEYMIK 15G
EPA Receipt Date: 30-Sep-2010
EPA Company Number: 87895
Company Name: AG LOGIC LLC

JANELLE KAY
PYXIS REGULATORY CONSULTING, INC
AG LOGIC LLC
4110 136TH ST. NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

The fee associated with this action is $ 4,578. Payment in the amount of $ 17,136 has been received. A refund in the amount of $ 12,558 will be issues when the action is completed.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,
Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{883212u~

This package includes the following

- (•) New Registration
- ( ) Amendment

[✓] Studies? [ ] Fee Waiver?

[ ] volpay % Reduction: ___

for Division

- ( ) AD
- ( ) BPPD
- (•) RD

Risk Mgr. 7

Receipt No. S- 883212

EPA File Symbol/Reg. No. 87895-R

Pin-Punch Date: 9/30/2010

[ ] This item is NOT subject to FFS action.

Action Code:

Requested: R330

Granted: R310

Amount Due: $ 4578

Parent/Child Decisions:

pre harvest food use

[☒] Inert Cleared for Intended Use [▨] Uncleared Inert in Product

Reviewer: JPM Date: 10/5/10

Remarks:

- product is not an MUP

R 310

Must submit Group A and B product chemistry data for each proposed product.
End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAI	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	✓					
830.1600	Description of materials used to produce the product	✓					
830.1650	Description of formulation process	✓					
830.1670	Discussion on the formation of impurities	✓					
830.1700	Preliminary analysis	✓					
830.1750	Certified limits (158.345)	✓					
830.1800	Enforcement analytical method	✓					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAI	
		Yes	No	Yes	No	Yes	No
830.6302	Color	✓					
830.6303	Physical State	✓					
830.6304	Odor	✓					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓					
830.6315	Flammability	✓					
830.6316	Explodability	✓					
830.6317	Storage stability	✓					
830.6319	Miscibility	✓					
830.6320	Corrosion Characteristics	✓					
830.6321	Dielectric Breakdown Voltage		×				
830.7000	pH	✓					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	✓					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	✓					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

N/A

Grayed out = data not required

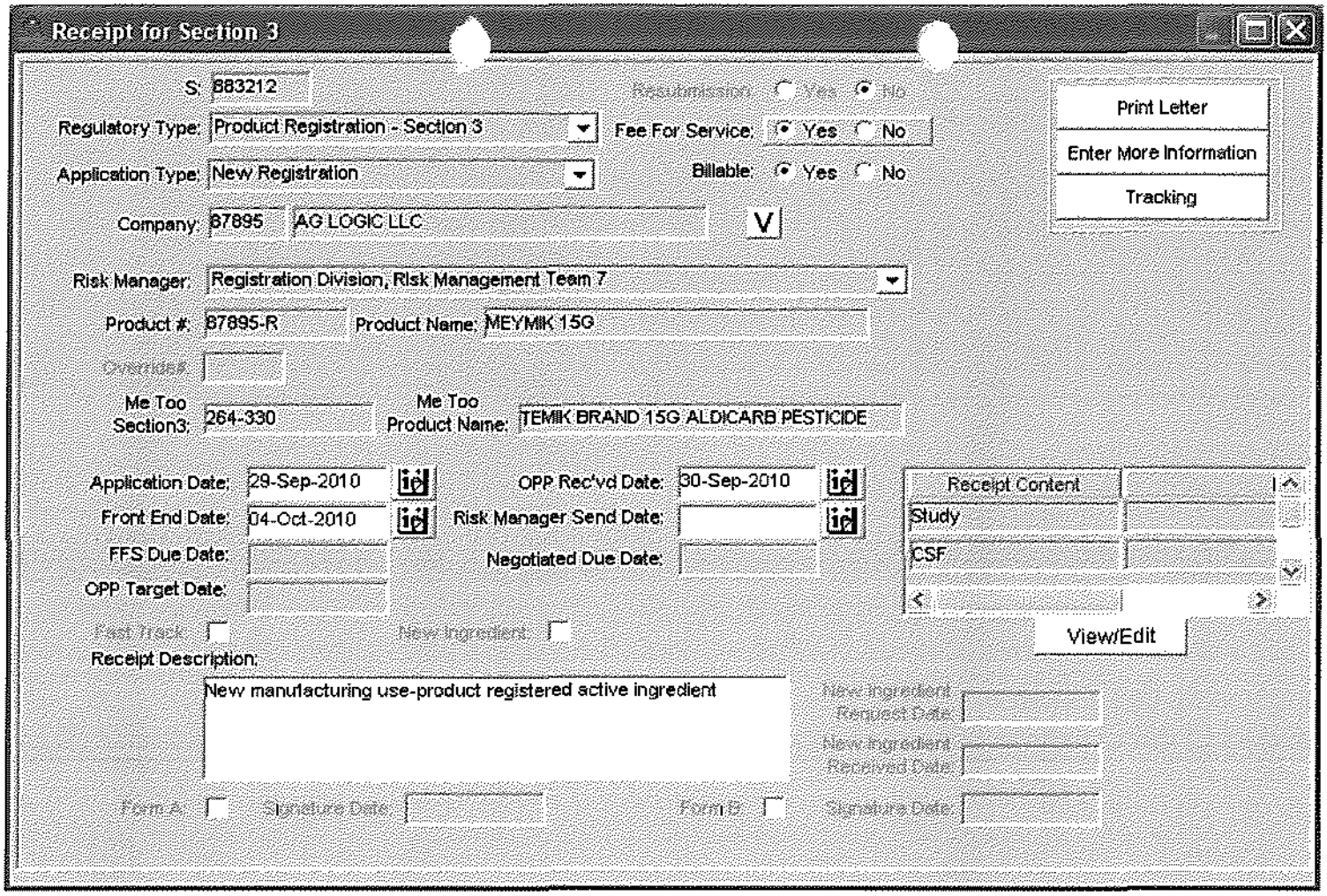
R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)	✓			
870.1200	Acute Dermal (LD50)	✓			
870.1300	Acute Inhalation (LC50)	✓			
870.2400	Acute Eye Irritation	✓			
870.2500	Acute Dermal Irritation	✓			
870.2600	Dermal Sensitization	✓			

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets					
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					


Receipt for Section 3
S: 883212
Resubmission: Yes No
Print Letter
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Enter More Information
Application Type: New Registration
Billable: Yes No
Tracking
Company: 87895 AG LOGIC LLC
V
Risk Manager: Registration Division, Risk Management Team 7
Product #: 87895-R
Product Name: MEYMIK 15G
Override:
Me Too Section3: 264-330
Me Too Product Name: TEMIK BRAND 15G ALDICARB PESTICIDE
Application Date: 29-Sep-2010
OPP Rec'vd Date: 30-Sep-2010
Front End Date: 04-Oct-2010
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
New manufacturing use-product registered active ingredient
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Online Payment

Step 3: Confirm Payment 1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25 tG6JKH
Agency Tracking ID: 74138734226
Transaction Date and Time: 09/16/2010 13:46 EDT

Payment Summary

Address Information

Account Holder Name: katherine g martyn
Billing Address: 121 s estes dr
Billing Address 2: suite 101
City: chapel hill
State / Province: NC
Zip / Postal Code: 27514
Country: USA

Account Information

Card Type: American Express
Card Number: ********** t035
Decision Number:
Registration Number:
Company Name: MEY Corporations
Company Number: 80967
Action Code: R330

Payment Information

Payment Amount: $17,136.00
Transaction Date and Time: 09/16/2010 13:46 EDT

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☑ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 87895-R
2. EPA Product Manager: J. Edwards
3. Proposed Classification: ☑ None ☐ Restricted
4. Company/Product tName: Ag Logic LLC/MEYMIK 15G
PM#: IKB
5. Name and Address of Applicant *(include ZIP Code)*:
Ag Logic LLC
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332
☐ *Check if this is a new address*
6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c))3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. 264-330
Product Name: Temik Brand 15G Aldicarb Pesticide

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in reponse to Agency letter dated _____
☑ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional pages if necessary. (For section I and Section II.)

This application falls under PRIA Category R330 (48: New manufacturing use-product; registered active ingredient; selective data citation) because it is an application for registration of new end use product which is substantially similar to a currently registered product. The fee has been paid ($17,136) and the decision time line is 12 months.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☑ Other (Specify) foil lined bags in cartons or polywoven supersaks
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☐ Label ☑ Container
4. Size(s) Retail Container: cartons: 30 lb., 40 lb.; supersak: 600 lb.
5. Location of Label Directions: ☑ On Label ☐ On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: ☑ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Ann M. Tillman	Agent	(253) 853-7369

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received: (Stamped)

2. Signature	3. Title
Ann M. Tillman	Agent
4. Typed Name	**5. Date**
Ann M. Tillman	9/29/10

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

September 29, 2010

OVERNIGHT DELIVERY

Joanne Edwards (IRB)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Ag Logic LLC
MEYMIK 15G (EPA File Symbol 87895-)
Application for New Pesticide Registration
PRIA Category R330

Dear Ms. Edwards,

On behalf of Ag Logic LLC, we are submitting an application for registration of MEYMIK 15G, an end use product containing the active ingredient aldicarb. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statements of Formula (EPA Form 8570-4) for Basic, Alternate #1, Alternate #2, Alternate #3 and Alternate #4
3. Three (3) Copies of the Proposed Labeling
4. A CD containing an electronic version of the label
5. Certification with Respect to Label Integrity
6. Agency Internal Use Copy of the Data Matrix
7. Public File Copy of the Data Matrix
8. Certification with Respect to Citation of Data (EPA Form 8570-34)
9. Copy of the PRIA payment
10. Letter of Authorization
11. Product Specific Data (3 copies each):

Volume 1	830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750, 830.1800	Tillman, A.M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Description of the Formulation Process, Discussion of the Formation of Impurities, Certified Limits and Enforcement Analytical Method for Aldicarb 15% G. ***Contains Confidential Business Information***
Volume 2	830.1700, 830.1800	Tillman, A. M. Preliminary Analyses of Five Representative Production Batches of Aldicarb Technical Grade Active Ingredient (TGAI) to Determine % Aldicarb and to Quantify its Associated Impurities. ***Contains Confidential Business Information.***

Volume 3	830.1700	Sinning, D. J. Aldicarb TGAI Preliminary Analysis. ***Contains Confidential Business Informotion.***
Volume 4	830.1800	Gual, J. Validation of the Assay Method of Aldicarb 15% G.
Volume 5	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7000, 830.7050, 830.7100, 830.7200, 830.7220, 830.7300, 830.7370, 830.7520, 830.7550-7570, 830.7840-7860, 830.7950	Tillman, A. M. Aldicarb Tech: Physical and Chemical Properties and Waiver Requests.
Volume 6	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7000, 830.7050, 830.7100, 830.7200, 830.7220, 830.7300, 830.7370, 830.7520, 830.7550-7570, 830.7840-7860, 830.7950	Tillman, A. M. Aldicarb 15% G: Physical and Chemical Properties and Waiver Requests.
Volume 7	870.1100, 870.1200, 870.1300, 870.2400, 870.2500, 870.2600	Tillman, A. M. Aldicarb 15% G Acute Toxicity.

We would like to note that Ag Logic LLC is using the selective method of support. Ag Logic LLC submitted notices of intent to apply and offers to pay to all companies on the March 31, 2010 Data Submitter's List. This action falls under Category R330 (48: New manufacturing use product; registered active ingredient; selective data citation). The PRIA fee due, $17,136, was paid inadvertently by an affiliate company (MEY Corporation; Company Number 80967) instead of by Ag Logic LLC. A copy of the receipt of payment is enclosed. The decision time line is 12 months.

We trust you will find this application complete. However, please feel free to contact me by email at Ann@PyxisRC.com or by phone at (253) 853-7369 if you have any questions or need any additional information.

Sincerely,

Ann M. Tillman

Enclosures

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Ag Logic, LLC c/o Pyxis Regulatory Consulting 4110 136th St. NW Gig Harbor, WA 98332 (253-853-7369)	87895-
Active Ingredient(s) and/or representative test compound(s) Aldicarb	Date 9/29/10
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food/feed crop	Product Name MEYMIK 15G

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Ann M Tillman	9/29/10	Ann M. Tillman, Agent

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date September 27, 2010	EPA Reg. No./File Symbol 87895-	Page / of 22
Applicant's/Registrant's Name & Address Ag Logic LLC 121 S. Estes Drive, Suite 101 Chapel Hill, NC 27514	Product MEYMIK 15G	

Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	Volume 1	Ag Logic LLC	OWN	
830.1600	Description of Materials Used to Produce the Product	Volume 1	Ag Logic LLC	OWN	
830.1620	Description of Production Process	Volume 1	Ag Logic LLC	OWN	
830.1650	Description of Formulation Process	Volume 1	Ag Logic LLC	OWN	
830.1670	Discussion of Formation of Impurities	Volume 1	Ag Logic LLC	OWN	
830.1700	Preliminary Analysis	Volumes 2, 3	Ag Logic LLC	OWN	
830.1750	Certified Limits	Volume 1	Ag Logic LLC	OWN	
830.1800	Enforcement Analytical Method	Volumes 1, 4	Ag Logic LLC	OWN	
830.6302	Color	Volumes 5, 6	Ag Logic LLC	OWN	
830.6303	Physical State	Volumes 5, 6	Ag Logic LLC	OWN	
830.6304	Odor	Volumes 5, 6	Ag Logic LLC	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Volumes 5, 6	Ag Logic LLC	OWN	

Signature	Name and Title	Date
	Ann M. Tillman, Consultant	Sept. 27, 2010

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date September 27, 2010	EPA Reg. No./File Symbol 87895-	Page 2 of 22
Applicant's/Registrant's Name & Address Ag Logic LLC 121 S. Estes Drive, Suite 101 Chapel Hill, NC 27514	Product MEYMIK 15G	

Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314	Oxidation/Reduction: Chemical Incompatibility	Volumes 5, 6	Ag Logic LLC	OWN	Waiver[1]
830.6315	Flammability	Volumes 5, 6	Ag Logic LLC	OWN	Waiver[2]
830.6316	Explodability	Volumes 5, 6	Ag Logic LLC	OWN	Waiver[3]
830.6317	Storage Stability	Volumes 5, 6	Ag Logic LLC	OWN	PRN 92-5[4]
830.6319	Miscibility	Volumes 5, 6	Ag Logic LLC	OWN	Not required[5]
830.6320	Corrosion Characteristics	Volumes 5, 6	Ag Logic LLC	OWN	PR-92-5[4]
830.6321	Dielectric Breakdown Voltage				Not Required[6]
830.7000	pH	Volume 3	Ag Logic LLC	OWN	
830.7050	UV/Visible Absorption	Volume 5	Ag Logic LLC	OWN	
830.7100	Viscosity	Volume 6	Ag Logic LLC	OWN	Not required[6]
830.7200	Melting Point/Melting Range	Volume 5	Ag Logic LLC	OWN	
830.7220	Boiling Point/Boiling Range				Not required[7]
830.7300	Density/Relative Density/Bulk Density	Volume 3	Ag Logic LLC	OWN	
830.7370	Dissociation Constants in Water	Volumes 5, 6	Ag Logic LLC	OWN	

Signature	Name and Title	Date
Ann M. Tillman	Ann M. Tillman, Consultant	Sept. 27, 2010

Form Approved OMB No. 2070-0060

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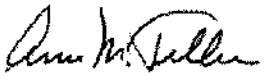
DATA MATRIX

Date September 27, 2010	EPA Reg. No./File Symbol 87895-	Page 2 of 22
Applicant's/Registrant's Name & Address Ag Logic LLC 121 S. Estes Drive, Suite 101 Chapel Hill, NC 27514	Product MEYMIK 15G	

Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7520	Particle Size, Fiber Length, and Diameter Distribution	Volumes 5, 6	Ag Logic LLC	OWN	Waiver[8]
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	Volume 5	Ag Logic LLC	OWN	
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	Volume 5	Ag Logic LLC	OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	Volume 5	Ag Logic LLC	OWN	
870.1100	Acute Oral Toxicity: Rat	Volume 7	Ag Logic LLC	OWN	

Signature	Name and Title	Date
	Ann M. Tillman, Consultant	Sept. 27, 2010

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date September 27, 2010	EPA Reg. No./File Symbol 87895-	Page 4 of 22
Applicant's/Registrant's Name & Address Ag Logic LLC 121 S. Estes Drive, Suite 101 Chapel Hill, NC 27514	Product MEYMIK 15G	

Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1200	Acute Dermal Toxicity: Rat	Volume 7	Ag Logic LLC	OWN	
870.1300	Acute Inhalation Toxicity: Rat	Volume 7	Ag Logic LLC	OWN	
870.2400	Primary Eye Irritation: Rabbit	Volume 7	Ag Logic LLC	OWN	
870.2500	Primary Dermal Irritation	Volume 7	Ag Logic LLC	OWN	
870.2600	Dermal Sensitization	Volume 7	Ag Logic LLC	OWN	
Generic Data Requirements					
850.2100 (71-1(a))	Acute Avian Oral Toxicity: Quail or Duck	Cite-all		PAY	
850.2200 (71-2(a))	Acute Avian Dietary Toxicity: Quail	00102132 1096727		OLD OLD	See endnote[9]

Signature	Name and Title	Date
Ann M. Tillman	Ann M. Tillman, Consultant	Sept. 27, 2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date September 27, 2010	EPA Reg. No./File Symbol 87895-	Page 5 of 22
Applicant's/Registrant's Name & Address Ag Logic LLC 121 S. Estes Drive, Suite 101 Chapel Hill, NC 27514	Product MEYMIK 15G	

Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2200 (71-2(b))	Acute Avian Dietary Toxicity: Duck	Cite-all		PAY	
850.2400 (71-3)	Wild Mammal Toxicity	Cite-all		PAY	
850.2300 (71-4(a))	Avian Reproductive Toxicity: Quail	Cite-all		PAY	
850.2300 (71-4(b))	Avian Reproductive Toxicity: Duck	Cite-all		PAY	
850.1075 (72-1(a),(b))	Fish Toxicity: Bluegill	40098001		OLD	See endnote[10]
850.1075 (72-1(c),(d))	Fish Toxicity: Trout	Cite-all		PAY	
850.1010 (72-2(a)(b))	Freshwater Invertebrate Toxicity	Cite-all		PAY	
850.1075 (72-3(a))	Estuarine/Marine Fish Toxicity	Cite-all		PAY	
850.1025 (72-3(b))	Estuarine/Marine Mollusk Toxicity	Cite-all		PAY	
850.1035 (72-3(c))	Estuarine/Marine Shrimp Toxicity	Cite-all		PAY	
850.1400 (72-4(a))	Early Life Stage: Fish Freshwater	Cite-all		PAY	
850.1400	Early Life Stage: Fish Saltwater	Cite-all		PAY	
850.1300 (72-4(b))	Aquatic Invertebrate Life Cycle (Freshwater)	00066341		OLD	See endnote[11]
850.1350	Aquatic Invertebrate Life Cycle (Saltwater)	Cite-all		PAY	
850.1500 (72-5)	Life Cycle Fish				Not required[12]

Signature	Name and Title	Date
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Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1710, 850.1730, 850.1850	Aquatic Organisms Bioavailability				Not required[13]
850.1950	Simulated or actual field testing for aquatic organisms				Not required[14]
850.1735	Whole sediment: Acute Freshwater Invertebrates				Not required[15]
850.1740	Whole sediment: Acute Marine Invertebrates				Not required[16]
850.3020 (141-1)	Acute Contact Toxicity: Honey Bee	Cite-all		PAY	
850.3030 (141-2)	Honey Bee Toxicity of Residues on Foliage	Cite-all		PAY	
870.6200 (81-8)	Acute Neurotoxicity (Rat)	Cite-all		PAY	
870.3100 (82-1(a))	90-Day Oral Toxicity in Rodents	Cite-all		PAY	
870.3150 (82-1(b))	90-Day Oral Toxicity in Non-Rodents	Cite-all		PAY	
870.3200 (82-2)	21-Day Dermal Toxicity			GAP	See endnote[17]
870.3250 (82-3)	90-Day Dermal Toxicity				Not required

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Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3465 (82-4)	90-Day Inhalation Toxicity			GAP	See endnote[18]
870.6200 (82-5(b))	90-Day Subchronic Neurotoxicity - Rat	43829602	Bayer CropScience LP	PAY	See endnote[19]
870.4100 (83-1(a))	Chronic Toxicity Rat	Cite-all		PAY	
870.4100 (83-1(b))	Chronic Toxicity Dog	Cite-all		PAY	See endnote[20]
870.4200 (83-2(a))	Carcinogenicity Rat	Cite-all		PAY	
870.4200 (83-2(b))	Carcinogenicity Mouse	Cite-all		PAY	
870.3700 (83-3)	Prenatal Development Toxicity Studies	Cite-all		PAY	
870.3800 (83-4)	Reproduction and Fertility Effects	Cite-all		PAY	
870.6300 (83-6)	Developmental Neurotoxicity Study	Cite-all		PAY	
870.5100 (84-2(a))	Bacterial Reverse Mutation Test	00148168		OLD	See endnote[21]
870.5300, 870.5375 (84-2(b))	*In vitro* Mammalian Cell Gene Mutation Test	Cite-all		PAY	
870.5385, 870.5395 (84-4)	*In vivo* Cytogenetics	Cite-all		PAY	
870.7200	Companion Animal Safety				Not required
870.7485	Metabolism and Pharmacokinetics	Cite-all		PAY	
870.7600 (85-2)	Dermal Penetration	Cite-all		PAY	

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Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7800	Immunotoxicity			GAP	See endnote[22]
N/A	Rat Dominant Lethal Study	43575101		OLD	See endnote[23]
N/A	Special Neurotoxicity Studies	45068601		PUBLIC	See endnote[24]
N/A	Acute Oral Studies (Human)	42373001 46131001	 Bayer CropScience LP	OLD PAY	See endnote[25]
N/A	Comparative Cholinesterase Assay	47994302 47994303 47994304 47994305	Bayer CropScience LP Bayer CropScience LP Bayer CropScience LP Bayer CropScience LP	PAY PAY PAY PAY	See endnote[26]
850.4100 (122-1(a))	Tier 1: Seed Germination and Seedling Emergence	Cite-all		PAY	
850.4150 (122-1(b))	Tier 1: Vegetative Vigor	Cite-all		PAY	
850.4400 (122-2)	Tier 1: Aquatic Plant Growth	Cite-all		PAY	

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Ingredient Aldicarb (CAS No. 116-06-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.1100	Dermal Outdoor Exposure	43852501 44793301	Bayer CropScience LP BASF Corporation	PAY PAY	See endnote[27]
875.1200	Dermal Indoor Exposure				
875.1300	Inhalation Outdoor Exposure	43852501 44793301	Bayer CropScience LP BASF Corporation	PAY PAY	See endnote[28]
875.1400	Inhalation Indoor Exposure				Not required
875.1500	Biological Monitoring				Not required
875.1600	Data Reporting and Calculations				Not required
875.1700	Product Use Information				Not required
875.2100 (132-1a)	Foliar Residue Dissipation	Cite-all		PAY	
875.2200	Soil Residue Dissipation				
875.2300	Indoor Surface Residue Dissipation				Not required
875.2400 (133-3)	Dermal Passive Dosimetry Exposure	Cite-all		PAY	
875.2500 (133-4)	Inhalation Passive Dosimetry Exposure	Cite-all		PAY	
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Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.2120 (161-1)	Hydrolysis	Cite-all		PAY	
835.2240 (161-2)	Photodegradation in Water	Cite-all		PAY	
835.2410 (161-3)	Photodegradation on Soil				Waived[29]
835.2370 (161-4)	Photodegradation in Air				Waived[30]

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Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.4100 (162-1)	Aerobic Soil Metabolism	00029989		OLD	See endnote[31]
		00093641		OLD	
		00096968		OLD	
		00102050		OLD	
		00101915		OLD	
		00102051		OLD	
		00102054		OLD	
		00035365		OLD	
		00101934		OLD	
		00102071		OLD	
		00053366		OLD	
		00080820		OLD	
		00093640		OLD	
		00093642		OLD	
		43805702	Bayer CropScience LP	PAY	
		44005001	Bayer CropScience LP	PAY	
		00053370		OLD	

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Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.4200 (162-2)	Anaerobic Soil Metabolism	Cite-all		PAY	
835.4300 (162-3)	Anaerobic Aquatic Metabolism	43805701 45592110 45582111	Bayer CropScience LP Bayer CropScience LP Bayer CropScience LP	PAY PAY PAY	See endnote[32]
835.4400 (162-4)	Aerobic Aquatic Metabolism	45592107 45592108 45582109	Bayer CropScience LP Bayer CropScience LP Bayer CropScience LP	PAY PAY PAY	See endnote[33]

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Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.1230, 835.1240 (163-1)	Leaching and Adsorption/Desorption	00053380		OLD	See endnote[34]
		00053381		OLD	
		00053385		OLD	
		00101915		OLD	
		00101939		OLD	
		00102079		OLD	
		42498202		OLD	
		43560301		OLD	
		43560302		OLD	
835.1410	Volatility – Laboratory				Not required
835.8100	Volatility – Field				Not required

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Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.6100 (164-1)	Soil Field Dissipation Study	00036313		OLD	See endnote[35]
		00053364		OLD	
		00068252		OLD	
		00080815		OLD	
		00101910		OLD	
		00101923		OLD	
		00101935		OLD	
		00101937		OLD	
		00102064		OLD	
		00101936		OLD	
		00101968		OLD	
		00102061		OLD	
		00102078		OLD	
835.6200 (164-2)	Aquatic Sediment Field Dissipation Study	Cite-all		PAY	
835.6300 (164-3)	Forest Field Dissipation Study				Not required

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Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.7100 (166-1)	Small-Scale Prospective Groundwater Study	46793702	Bayer CropScience LP	PAY	See endnote[36]
		46793703	Bayer CropScience LP	PAY	
		46793704	Bayer CropScience LP	PAY	
		46793705	Bayer CropScience LP	PAY	
		46793706	Bayer CropScience LP	PAY	

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Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1300 (171-4(a))	Nature of Residue in Plants	00053358 00053364 00053366 00053368 00085455 00101929 00101930 00101931 00101977 00101996 00102009 00102178 42436602 42436603 42436604 42436605 42436606		OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD	See endnote[37]
860.1300 (171-4(b))	Nature of Residue in Livestock	Cite-all		PAY	

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Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1340 (171-4(c))	Residue Analytical Method (Plant)	00025167		OLD	See endnote[38]
		00036315		OLD	
		00069739		OLD	
		00069740		OLD	
		00101973		OLD	
		00101978		OLD	
		00101992		OLD	
		00101993		OLD	
		00101997		OLD	
		00101998		OLD	
		00101999		OLD	
		00102004		OLD	
		00102005		OLD	
		00102007		OLD	
		00104553		OLD	
		00135031		OLD	
		00140487		OLD	
		42436501		OLD	

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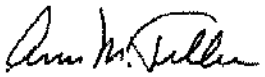
Ingredient Aldicarb (CAS No. 116-06-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1340 (171-4(d))	Residue Analytical Method (Livestock)	Cite-all		PAY	
860.1340 (171-4(d))	Residue Analytical Method (Water/Fish)	Cite-all		PAY	
860.1360 (171-4(m))	Multiple Residue Method	Cite-all		PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Oate Sept. 27, 2010

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Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1380 (171-4(e))	Storage Stability	PP#0F1008		OLD	See endnote[39]
		PP#9F0798		OLD	
		PP#3F1414		OLD	
		PP#7E1996		OLD	
		PP#6F1953		OLD	
		PP#7F1995		OLD	
		PP#8F2107		OLD	
		PP#8F0637		OLD	
		PP#9F2201		OLD	
		PP#6E1792		OLD	
		PP#8F2096		OLD	
		FAP#6H5108		OLD	
		00159571		OLD	
		42467301		OLD	
		42457302		OLD	
		43844701	Bayer CropScience LP	PAY	
		43299005		OLD	
		43299006		OLD	
		48156902	Bayer CropScience LP	PAY	

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Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1400 (171-4(h))	Nature and Magnitude of the Residue in Water, Fish, and Irrigated Crops				Not required
860.1460 (171-4(i))	Magnitude of the Residue in Food Handling Establishments				Not required
860.1480 (171-4(j))	Magnitude of the Residue in Meat, Milk and Eggs	Cite-all		PAY	
860.1500 (171-4(k))	Magnitude of the Residue in Cotton	Cite-all		PAY	
860.1500 (171-4(k))	Magnitude of the Residue in Dry Beans	Cite-all		PAY	
860.1500 (171-4(k))	Magnitude of the Residue in Peanuts	Cite-all		PAY	
860.1500 (171-4(k))	Magnitude of the Residue in Soybeans	Cite-all		PAY	
860.1500 (171-4(k))	Magnitude of the Residue in Sugar Beets	Cite-all		PAY	
860.1500 (171-4(k))	Magnitude of the Residue in Sweet Potatoes	PP#7F1995 42722301		OLD OLD	
860.1520 (171-4(l))	Magnitude of the Residue in Processed Food/Feed in Cotton	Cite-all		PAY	

Signature	Name and Title	Date
Ann M. Tillman	Ann M. Tillman, Consultant	Sept. 27, 2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date September 27, 2010			EPA Reg. No./File Symbol 87895-		Page 2 of 22
Applicant's/Registrant's Name & Address Ag Logic LLC 121 S. Estes Drive, Suite 101 Chapel Hill, NC 27514			Product MEYMIK 15G		
Ingredient Aldicarb (CAS No. 116-06-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1520 (171-4(l))	Magnitude of the Residue in Processed Food/Feed in Peanuts	Cite-all		PAY	
860.1520 (171-4(l))	Magnitude of the Residue in Processed Food/Feed in Soybeans	Cite-all		PAY	
860.1520 (171-4(l))	Magnitude of the Residue in Processed Food/Feed in Sugar Beets	Cite-all		PAY	
860.1850 (165-1)	Confined Rotational Crops	Cite-all		PAY	
860.1900 (165-2)	Field Rotational Crops	Cite-all		PAY	
201-1	Droplet Size Spectrum	Cite-all		PAY	
202-1	Droplet Size Spectrum	Cite-all		PAY	
Aldicarb Product Specific Acute Toxicity and Generic Data Requirements					
Ag Logic, LLC will make offers-to-pay to the following companies on the aldicarb data submitters list of March 31, 2010.					
Signature			Name and Title Ann M. Tillman, Consultant		Date Sept. 27, 2010

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
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DATA MATRIX

Date September 27, 2010	EPA Reg. No./File Symbol 87895-	Page 22 of 22
Applicant's/Registrant's Name & Address Ag Logic LLC 121 S. Estes Drive, Suite 101 Chapel Hill, NC 27514	Product MEYMIK 15G	

Ingredient Aldicarb (CAS No. 116-06-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Bayer CropScience LP	PAY	
		Cite-All	E.I. du Pont de Nemours and Co., Inc.	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	Outdoor Residential Exposure Task Force	OWN	See endnote[40]
		Cite-All	Agricultural Reentry Task Force.	OWN	See endnote[40]
		Cite-All	FIFRA Endangered Species Task Force	PAY	
		Cite-All	Residential Exposure Joint Venture	PAY	
		Cite-All	Agricultural Handlers Exposure Task Force	PAY	

Signature	Name and Title	Date
Ann M. Tillman	Ann M. Tillman, Consultant	Sept. 27, 2010

Endnotes for Data Matrix for MEYMIK 15G

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[1] **830.6314** - Ag Logic LLC requests a waiver from this data requirement due to the fact that Aldicarb Tech is not stored but rather converted immediately to the end use product MEYMIK 15G.

[2] **830.6315** - Ag Logic LLC requests a waiver from this data requirement due to the fact that Aldicarb Tech is a solid and is not stored but rather converted immediately to the end use product MEYMIK 15G.

[3] **830.6316** - Ag Logic LLC requests a waiver from this data requirement due to the fact that Aldicarb does not contain the chemical bonds or functional groups associated with explosive compounds.

[4] **830.6317, 830.6320** - Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Ag Logic LLC has initiated these studies and will submit these data when the studies are completed.

[5] **830.6319** - This data requirement is required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. MEYMIK 15G is a solid and therefore this data requirement is not required.

[6] **830.6321** - These data are required if the product is an end-use product to be used around electrical equipment. This data requirement is not applicable to MEYMIK 15G because it will not be applied around electrical equipment.

[7] **830.7220** – These data are only required for liquids. Aldicarb Tech is a solid. Refer to melting point data.

[8] **830.7520** - Ag Logic LLC is seeking a waiver for this data requirement for Aldicarb Tech and MEYMIK 15G because the products are not fibrous materials and they are not water insoluble.

[9] **850.2200 (71-2(a))** – The studies cited were listed in the RED as satisfying the data requirement.

[10] **850.1075 (72-1(a,b))** – The study cited was listed in the RED as satisfying the data requirement.

[11] **850.1300 (72-4(b))** – The study cited was listed in the RED as satisfying the data requirement. In addition, page 34 of EFED Risk Assessment for the RED stated that EEB would consider this guideline requirement waived (saltwater invertebrate data will be used for the endpoint).

[12] **850.1500 (72-5)** – These data were not required in the RED.

[13] **850.1710, 850.1730, 850.1850** – These data were not required in the RED.

[14] **850.1950** – These data were not required in the RED.

[15] **850.1735** – These data were not required in the RED.

[16] **850.1740** – These data were not required in the RED.

[17] **870.3200 (82-2)** – The risk assessment for the RED identified these data as a data gap and that there were no acceptable data to satisfy the guideline requirement.

[18] **870.3465 (82-4)** – The risk assessment for the RED identified these data as a data gap and that there were no acceptable data to satisfy the guideline requirement.

[19] **870.6200 (82-5(b))** – The study cited was listed in the RED as satisfying the data requirement.

[20] **870.4100 (83-1(b))** – Ag Logic LLC recognizes that these data are no longer required to support registration. However, in an effort to expeditiously obtain the registration, Ag Logic has elected to use cite-all under selective method for this guideline.

[21] **870.5100 (84-2(a))** – The study cited was listed in the RED as satisfying the data requirement.

[22] **870.7800** – Immunotoxicity data are a new data requirement promulgated in 40 CFR in 2007. Ag Logic will commit to conducting this study as a condition for registration.

[23] **Rat Dominant Lethal Study** – The study cited is listed in the RED as being required to support an aldicarb registration.

Endnotes for Data Matrix for MEYMIK 15G

[24] **Special Neurotoxicity Studies** – The study cited is listed in the RED as being required to support an aldicarb registration.

[25] **Acute Oral Studies (Human)** – The studies cited are listed in the RED as being required to support an aldicarb registration.

[26] **Comparative Cholinesterase Assay** – The studies cited are acceptable and meet the special DCI from the RED as per a July 13, 2010 EPA review.

[27] **875.1100** – The studies cited are listed in the RED as being required to support an aldicarb registration.

[28] **875.1300** – The studies cited are listed in the RED as being required to support an aldicarb registration.

[29] **835.2410 (161-3)** – According to the RED, this guideline requirement is waived.

[30] **835.2370 (161-4)** – According to the RED, this guideline requirement is waived.

[31] **835.4100 (162-1)** – The studies cited are listed in the RED as being required to support an aldicarb registration.

[32] **835.4300 (162-3)** – The studies cited are listed in the RED as being required to support an aldicarb registration.

[33] **835.4400 (162-4)** – The studies cited are listed in the RED as being required to support an aldicarb registration. Note: 45592107 was not listed in the RED (indeed, no aldicarb specific data were listed in the RED. As such, the most recent aldicarb study was cited here).

[34] **835.1230, 835.1240 (163-1)** – The studies cited are listed in the RED as being required to support an aldicarb registration.

[35] **835.6100 (164-1)** – The studies cited are listed in the RED as being required to support an aldicarb registration.

[36] **835.7100 (166-1)** – The studies cited are listed in the RED as being required to support an aldicarb registration.

[37] **860.1300 (171-4(a))** – The studies cited are listed in the RED as being required to support an aldicarb registration. Note: MRID number 43902401 was not cited as this study was conducted in lemons and MEYMIK 15G is not proposed for use on citrus. Therefore, this study is not relevant to Ag Logic's proposed uses.

[38] **860.1340 (171-4(c))** – The studies cited are listed in the RED as being required to support an aldicarb registration.

[39] **860.1380 (171-4(e))** – The studies cited are listed in the RED as being required to support an aldicarb registration. An additional study, MRID 48156902, was also cited because these data appear to be submitted in response to data required in the RED. Finally, MRID number 43842401 was not cited as this study was conducted with coffee beans. MEYMIK 15G is not proposed for use on coffee. Therefore, this study is not relevant to Ag Logic's proposed uses.

[40] Ag Logic LLC, through its affiliation with MEY Corporation, is a member/licensee of the following task forces and as such, offer-to-pay letters are not required: ORETF, ARTF.

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL

EPA Registration #	Date Submitted to EPA	Electronic file name
087895-xxxxx	Sept. 29, 2010	087895-xxxxx.20100927.MEYMIK 15G label v1.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature
Ann M. Tillman
Agent, Ag Logic, LLC

Sept. 29, 2010
Date

PROCESSING ELECTRONIC LABELS

(rev. 1/5/09, tch)

If e-label submitted via XML e-submission (not on CD-ROM), you may wish to find e-label in Documentum, save e-label to "My Documents", add e-label to ELL, start below at step 5.

Initial E-Label per application (on CD-ROM with paper via ITRMD)

1 ITRMD receives paper submission w/ e-label on CD

2 Tracking record added to OPPIN

3 ITRMD adds e-label to ELL

4 ITRMD sends paper submission to AD/BPPD/RD

5 Connect ELL record with OPPIN S#

in-process

6 Save copy of e-label from ELL to My Documents

7 Review label

(if acceptable, skip to step 20)

8 Add comments to e-label

(save; add "with comments" to filename

9 Print annotated e-label

(use "Print with Filename")

review

10 Send annotated e-label to registrant via email

(also send "How To Print")

11 File print of annotated e-label and email in jacket

12 Add annotated e-label to ELL

13 Close submission in OPPIN

out-process

Resubmission (via email to staffer or PM)

14 Receive email submission w/ e-label attached

15 Add tracking record to OPPIN

16 Add e-label to ELL

17 Connect ELL record with OPPIN S#

in-process

18 Save copy of e-labels (old & new) from ELL to My Documents

19 Compare old and new labels with Acrobat

(if revisions needed repeat steps 8-19)

review

20 Print e-label, stamp, write cover letter

(use "Print with Filename")

21 Mail stamped label & cover letter to registrant

22 File stamped label & cover letter in jacket

23 Add cover letter to ELL

(mandatory if accepted with comments)

24 Close submission in OPPIN

out-process

process - big picture

1- create OPPIN tracking
2- put label in ELL; link to S#
3- save ELL label to MyDocuments
4- compare / comment
5- outprocess

techniques to know

- filename for e-labels
- "print with filename"
- compare / comment
- printing with comments

AgLOGIC LLC

121 S. Estes Drive, Suite 101
Chapel Hill, NC 27514
(919) 932-5800

September 10, 2010

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agents for AgLOGIC (EPA Company Number pending), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Antoine A Puech, PhD
President, AgLogic LLC

cc: Pyxis Regulatory Consulting, Inc.

Aventis CropScience

EPA Correspondence No. 02-18A
September 24, 2002

Ms. Joanne Edwards
Registration Division (H7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Re: EPA Registration of Generic "Me-Too" Granular Aldicarb Products

Dear Ms. Edwards:

This letter is sent in anticipation that an application for a me-too registration for a granular aldicarb product may soon be made to the Registration Division of the Office of Pesticide Programs. Also, Aventis CropScience expects that the me-too applicant will cite the aldicarb and TEMIK® data on file with the EPA in support of such an application, including exposure data that pertain to the formulation of the aldicarb end-use products sold under the brandname, TEMIK®. In the alternative, the me-too applicant may cite the exposure data in the PHED database in support of this application.

In this context, the purpose of this letter is threefold. First, Aventis CropScience is informing EPA that Aventis has not authorized any me-too applicant to use or otherwise rely upon any aldicarb or TEMIK® data currently on file with the EPA in support of a me-too application for a granular aldicarb product. Second, for reasons that are set forth in this letter, Aventis is advising the EPA that it would be inconsistent with the requirements of FIFRA § 3(c)(7)(A) for the EPA to rely on the aldicarb and TEMIK® data in support of an application for a me-too registration of aldicarb. Because of differences in the composition of any anticipated me-too aldicarb product, its composition will not be substantially similar to the existing Aventis TEMIK® product, and the generic product will result in higher exposure to mixer/loader and applicators working with the product. Thirdly, Aventis is also advising EPA that, as explained in this letter, reliance on the PHED exposure data on part of the me-too applicant leads to the conclusion that handler exposure to the generic granular aldicarb presents unacceptable risk.

The TEMIK® Formulations

The current TEMIK® formulations have been designed to minimize exposure to aldicarb. Using state-of-the-art trade secret formulation technology, Aventis produces a granular formulation that essentially encapsulates the aldicarb and the gypsum carrier on which aldicarb is deposited. As this technology has been developed and applied over a period of 30 years it would not be an easy matter for a me-too applicant to develop such technology, and the EPA should be cautious about any representations to the contrary. Aventis has invested millions of dollars in perfecting the current trade secret TEMIK® formulations and has not shared the formulation process with anyone outside the company. Aventis is the only manufacturer using this formulation process.

The TEMIK® formulation technology incorporates a strict internal standard for dust content. This standard is [redacted] Dust analysis of TEMIK® 15G on file with the EPA measured dust levels in this formulation at [redacted] on average (TEMIK® Brand 15G Quality Control Data on Dust Control of Gypsum and Grit Formulations, MRID 45079706). In fact, the dust level for 99% of TEMIK® 15G production is less than [redacted] Most importantly, any TEMIK® 15G product with a dust content at or above [redacted] is recycled (remanufactured) and not sold. In contrast, dust analysis of a generic formulation of a 15% aldicarb granular product obtained on the global market from a producer of generic aldicarb showed dust levels of 0.18% and 0.37% of the formulation, a significantly higher amount of dust that will produce higher and unacceptable levels of exposure to aldicarb by mixer/loader and applicators of that product.

Furthermore, from dust analysis of MOCAP® 10G[1], an Aventis granular product containing the active ingredient ethoprop, Aventis has quantified the dust levels in this product at [redacted] on average. Thus the generic granular aldicarb formulation and the MOCAP® 10G formulation have similar dust levels which are both significantly higher than the TEMIK® 15G formulation. Both of these dusty formulations are equally unacceptable. Consequently, as part of the ethoprop reregistration agreement, Aventis volunteered to cancel the registration for MOCAP® 10G by December 31, 2001.

Exposure Data For Granular Products

Aventis has conducted a mixer/loader and applicator exposure study for TEMIK® 15G (MRID 43852501), which has been reviewed and accepted by EPA. This study shows that the dermal and inhalation exposure levels for TEMIK® 15G are approximately 100 times lower than typical granular formulations such as MOCAP® 10G and the granular formulations from which the limited PHED exposure data was generated.

Upon comparing the data from the MOCAP®10G worker exposure study (MRID 44984101) with the PHED granular worker exposure data, one finds almost identical dermal and inhalation exposure potential to the mixer/loader and applicators. Since the dust content of the generic granular aldicarb product has been demonstrated to be similar to the MOCAP® 10G product, the exposure potential for the MOCAP® 10G product would be the same for the generic aldicarb product. Although PHED data are not applicable to TEMIK® brand products, the PHED exposure data do apply to generic granular aldicarb formulations, which have a dust content similar to MOCAP® 10G. If exposure potential for a generic granular aldicarb formulation is calculated using PHED data, it is similar to the exposure calculated for MOCAP® 10G and approximately 100 times greater than TEMIK® 15G under comparable use conditions.

As previously noted, this fact leads to the conclusion that a generic granular aldicarb formulation, with an exposure profile calculated using the PHED exposure data, would present an unreasonable risk to the mixer/loaders and applicators of that formulation. As already mentioned, the worker exposure risk assessment to MOCAP® 10G was unacceptable and Aventis volunteered to cancel the registration.

It should be noted that the company experienced several overexposure incidents in the agricultural and specialty markets with the introduction of TEMIK® in the 1970's due to dust and other problems associated with the formulations. Significant efforts made to improve the formulations have lead to a dramatic reduction in dust in the current TEMIK® formulations. As a result of these changes, the incidents of worker overexposure to TEMIK® have been reduced to an average of less than one overexposure per year for the last 10 years. The opposite effect, an increase in incidents, would occur

[1] MOCAP® 10G is a granular product composed of the active ingredient ethoprop (an organophosphate insecticide) formulated on a clay substrate.

should the EPA register a generic aldicarb formulation that is not formulated with technology comparable to the Aventis technology. This generic granular aldicarb formulation would almost certainly have a higher dust level, thus a greater exposure potential and thus a higher incidence of overexposure. Aventis is properly concerned that, in the event of such an increase in exposure incidents, users may not distinguish between TEMIK® products and the generic aldicarb product that produces higher exposure. It is important the EPA carefully consider whether the risk to the mixer/loader and applicators is unreasonable given the benefits from the use of such a generic aldicarb formulation and assure that these products are regulated on the basis of data that accurately represents the differing composition of the products.

The "Identical and Substantially Similar" Requirements of FIFRA § 3(c)(7)(A)

FIFRA § 3(c)(7)(A) requires EPA to determine whether a "me-too" pesticide is identical or substantially similar to a currently registered pesticide prior to approving the application for registration. FIFRA § 3(c)(7)(A) permits the EPA to "conditionally register . . . a pesticide if the Administrator determines that (i) the pesticide and proposed uses are identical or substantially similar to any currently registered pesticide and use thereof . . ." The EPA "will not approve the conditional registration of any pesticide under FIFRA § 3(c)(7)(A) unless the Agency has determined that the applicant's product and its proposed uses are identical or substantially similar to a currently registered pesticide and use . . ." See 40 C.F.R. § 152.113(b).

"Identicality"

To determine identicality prior to registration, the EPA compares the composition of the me-too pesticide to the composition of the currently registered pesticide (Standard Operating Procedure, Number: 3068.2, July 1, 1981). This SOP "calls for an initial examination of the composition of an applicant's product and then a comparison of the ingredients in the applicant's product with the ingredients in currently registered products". Applying this SOP, the EPA determines whether the me-too pesticide is the same or different from currently registered pesticides.

As noted, a generic aldicarb formulation would have a greater dust content than TEMIK® 15 G. This fact alone demonstrates that such a generic formulation would not be identical to TEMIK® 15G which is produced using trade secret formulation technology.

"Substantially Similar"

Absent identicality, a me-too pesticide can be registered only if it is substantially similar to the currently registered pesticide. The me-too achieves "substantially similar" status only when differences in composition do not significantly increase the risk of unreasonable adverse effects on the environment as shown by the results of an incremental risk assessment. See 40 C.F.R. § 152.113.

The greater dust content associated with a generic granular aldicarb formulation does, in fact, represent a difference in composition and requires that EPA determine whether this difference significantly increases the risk of unreasonable adverse effects on the environment. To answer this question, EPA must conduct an incremental risk assessment.

To conduct this incremental risk assessment, the EPA must have valid scientific data in its possession. In this instance, the applicant seeking registration of any generic granular aldicarb product must supply dust and exposure data on its generic aldicarb formulation provided by the me-too registrant. If it does not provide data on its specific formulation, it must rely on the PHED exposure data. Either method of fulfilling the data requirements would allow the EPA to determine whether the generic granular aldicarb formulation can be registered in compliance with the FIFRA§ 3(c)(7)(A).

The dust and exposure data on file with the EPA for TEMIK® 15G are not suitable for conducting an incremental risk assessment for a generic granular aldicarb product. The EPA has determined from the TEMIK® 15G exposure data (MRID 43852501) that the use of TEMIK® 15G does not generally pose unreasonable adverse effects to the mixer/loader and applicator. The risk analysis that led to this determination can not be applied to a generic aldicarb formulation, which has a greater dust content than that of TEMIK® 15G, and therefore a greater exposure potential. This greater exposure potential presents
a significantly different risk profile for such a generic aldicarb formulation than for TEMIK® 15G. Given this point, the use of the TEMIK® 15G dust and exposure data to conduct such an incremental risk assessment would be an invalid scientific exercise and not satisfy the requirements of FIFRA§ 3(c)(7)(A).

Conclusion

If an applicant does apply for registration of a generic granular aldicarb product, the EPA must require the applicant to present data on the dust content of its granular formulation. Should the dust content of the generic granular aldicarb product be significantly greater than that of the TEMIK® 15G formulation, the EPA must require exposure data for mixer/loader and applicator. This data is necessary for the EPA to perform an incremental risk analysis to determine whether the generic aldicarb formulation significantly increases the risk of any unreasonable adverse effect to workers or to the environment. Such an incremental risk analysis would be necessary for compliance with the registration requirements of FIFRA § 3(c)(7)(A), the section of FIFRA under which the generic aldicarb formulation would be registered. The aldicarb dust (MRID 45079706) and exposure data (MRID 43852501) cannot be used for this purpose because of the lack of substantial similarity between the TEMIK®15G and the generic granular aldicarb formulation.

Given the potentially significant toxicological and environmental consequences resulting from the registration of a generic me-too product that is not comparable to TEMIK®, the EPA must conduct an incremental risk analysis using valid scientific studies submitted by the generic me-too registrant. Such conduct is required to ensure that the generic me-too product does not pose an unreasonable risk to workers or the environment. If the EPA registers a generic me-too granular aldicarb product without first making this detailed assessment it is likely that there will be a significant increase in incidents of overexposure to workers using the generic me-too product and that the reputation of both Aventis and the EPA will be negatively impacted because the public will not distinguish between TEMIK®15G and a generic aldicarb product. In order to avoid confusing the public and to meet its statutory obligations for registering generic pesticides, EPA must assure that an applicant to register generic aldicarb submits data on its own formulation to the extent that its product is not substantially similar to existing aldicarb products.

I can be reached at 919-549-2870. Please contact me if you have any questions regarding this letter.

Sincerely,

L. R. Hodges

Larry R. Hodges, Ph.D.
Registration Manager

cc: Meredith Laws
Jeffrey Dawson
Jeffrey Evans
John Redden

Pages 195-198 - *Confidential Statements of Formula may be entitled to confidential treatment*